PRN®
PHARMACAL

# 2020 Product Catalog

JANUARY EDITION

# As needed, when needed.

**In 1978**, four men, fueled by the belief that the veterinary community needed a company to service their unmet needs, each put in $5,000, their industry-specific expertise and a huge dose of optimism to found such a company. This company's business would be dedicated to leading the industry in research and development of niche products and drug therapies that address overlooked areas of pet and animal health.

***Pro Re Nata*** is a Latin phrase meaning as the circumstance arises. It has come to be used in prescription medicine as p.r.n. or ***as needed***. This is how PRN® Pharmacal began and it is how we continue to view ourselves today. As true as it was in 1978, the veterinary community can be assured that PRN Pharmacal will be here when needed to provide products that improve animal health and quality of life.

Under the **highest quality and rigor of Current Good Manufacturing Practices (cGMP)* and standards**, we strive to provide a wide range of products for the enhancement of animal health in areas of veterinary medicine that are largely under-served. Our mission is to continually improve our products and services to meet the needs of the veterinary industry, and is driven by both our **employee-ownership** and a fundamental set of values.

***Quality comes first.***
*To achieve customer satisfaction, the quality of our products and services must be our number one priority.*

***Continuous improvement.***
*Knowing that it is essential to our success, we must strive for excellence in everything we do: in our products, in their safety and value – and in our competitiveness.*

***Our veterinary industry customers are our partners.***
*Whether that be veterinarians, distributors, dealers or suppliers, the company must maintain mutually beneficial relationships with those partners and our business associates.*

Our dedication to animal health goes beyond mission statements and company mottos. We are constantly seeking new, unique products, as well as improvements on formulations, packaging, palatability and ease of use. We know that to grow, we have to meet the needs of companion animals and livestock, the veterinarians who treat them and the owners who rely on animals for their livelihood and companionship. It has been that way from our beginning and will continue that way into our future…

***… As needed, when needed.***

PRN® PHARMACAL

* Current Good Manufacturing Practice regulates minimum requirements for the methods, facilities and controls used in manufacturing, processing and packaging of a drug product. The regulations make sure that a product is manufactured under consistent quality standards, and that it has the highest ingredients and strength it claims to have.

## Contents

# Can you guess the No.1 medical conditions in dogs and cats?

*The results are in for the top medical conditions and the average cost to treat. Does the list match up with what you see most in your veterinary practice?*

***Quick Note:*** *These results are based on 1.6 million pet insurance claims submitted members of to the North American Pet Health Insurance Association (NAPHIA) in the United States*[1].

[1] *State of the Industry Report 2017, North American Pet Health Insurance Association*

## Top Medical Conditions In Dogs

| Condition | Average Annual Treatment Cost Per Pet |
|---|---|
| Ear Infection | $149.30 |
| Allergies | $234.84 |
| Skin Infection | $175.97 |
| Upset Stomach | $385.46 |
| Diarrhea | $203.14 |
| Bladder Issues | $617.17 |
| Eye Infection | $115.45 |
| Arthritis | $255.75 |
| Hypothyroidism | $123.29 |
| Sprains | $267.17 |

## Top Medical Conditions In Cats

| Condition | Average Annual Treatment Cost Per Pet |
|---|---|
| Urinary Tract Condition | $295.18 |
| Upset Stomach | $385.46 |
| Renal Failure | $485.38 |
| Diarrhea | $203.14 |
| Allergies | $234.84 |
| Diabetes | $276.39 |
| Colitis | $203.14 |
| Ear Infections | $149.30 |
| Upper Respiratory Infections (URI) | $219.27 |
| Hyperthyroidism | $215.75 |

# Urinary Health


## CitraVet®

***Potassium Citrate Tablets***

**USES** *CitraVet® uses potassium citrate to increase the urine alkalinity in the bladder. CitraVet can be part of a maintenance program for dogs and cats that require urine pH management. CitraVet tablets are highly palatable, liver-flavored, and double scored for easy dosing.*

| Item # | Product Name | Supplied |
|---|---|---|
| *30032848* | *CitraVet® Tabs* | *60 ct. bottle* |


## CranMate®

***Nutritional Supplement***

**USES** *CranMate® Nutritional Supplement is formulated specifically to support a healthy urinary tract in dogs and cats. Made with American cranberry extract and rich in Type-A proanthocyanidins (PACs) and antioxidants.*

| Item # | Product Name | Supplied |
|---|---|---|
| *30032648* | *CranMate® Tablets* | *60 ct. bottle* |






## PROIN ER™

***(phenylpropanolamine hydrochloride extended-release tablets)***

**INDICATIONS** *PROIN ER™ (phenylpropanolamine hydrochloride extended-release tablets) provides the same proven efficacy as PROIN® (phenylpropanolamine hydrochloride) in extended-release tablets for once-a-day dosing.[1] Our patented extended-release technology provides a controlled release mechanism that achieves steady absorption.*

| Item # | Product Name | Supplied |
|---|---|---|
| *30034457* | *PROIN ER™ 18mg Tablets* | *30 ct. bottle* |
| *30034557* | *PROIN ER™ 38mg Tablets* | *30 ct. bottle* |
| *30034657* | *PROIN ER™ 74mg Tablets* | *30 ct. bottle* |
| *30034757* | *PROIN ER™ 145mg Tablets* | *30 ct. bottle* |

**REFERENCES:** 1. Pegasus Laboratories, Inc (2019). *Freedom of Information (FOI) Summary for PROIN ER™ (phenylpropanolamine hydrochloride extended-release tablets) Dogs: US, (NADA 141-517).* Center for Veterinary Medicine (CVM).

**IMPORTANT SAFETY INFORMATION:** For oral use in dogs only. Not for human use. Keep out of reach of children. If accidentally ingested by humans, contact a physician immediately.

The most commonly reported side effects were vomiting, loss of appetite, diarrhea, excessive salivation, agitation, tiredness, vocalization, confusion, increased water consumption, weight loss, weakness, fever, panting, and reversible changes in skin color (flushing or bright pink). Abnormal gait, seizures or tremors, as well as liver enzyme elevations, kidney failure, blood in urine and urine retention have been reported. In some cases death, including euthanasia has been reported. Sudden death was sometimes preceded by vocalization or collapse.

Instances of dogs chewing through closed vials of PROIN® and eating the vial contents have been reported, in some cases resulting in overdose. Keep the product in a secured storage area out of the reach of pets in order to prevent accidental ingestion or overdose, as dogs may willingly consume more than the recommended dosage of PROIN® Chewable Tablets or PROIN ERTM tablets. Contact your veterinarian immediately if the dog ingests more tablets than prescribed or if other pets ingest PROIN Chewable tablets or PROIN ER tablets.

PROIN and PROIN ER may cause elevated blood pressure and should be used with caution in dogs with pre-existing heart disease, high blood pressure, liver disease, kidney insufficiency, diabetes, glaucoma, and other conditions associated with high blood pressure. Dogs may transition from PROIN Chewable Tablets to PROIN ER without a break in administration. However, do not alternate PROIN ER with PROIN Chewable Tablets because the effectiveness and safety of interchangeable use have not been evaluated.

The safe use of PROIN and PROIN ER in dogs used for breeding purposes, during pregnancy or in lactating bitches, has not been evaluated. Contact your veterinarian if you notice restlessness or irritability, loss of appetite, the incontinence persists or worsens, or any other unusual signs. See prescribing information for complete details regarding adverse events, warning and precautions or visit prnpharmacal.com.


## PROIN®

***(phenylpropanolamine hydrochloride) Chewable Tablets***

**INDICATIONS** *PROIN® (phenylpropanolamine hydrochloride) chewable tablets is the only FDA-approved PPA for the treatment of urinary incontinence due to urethral sphincter hypotonus. Liver-flavored tablets are available in three sizes and scored for precise dosing.*

| Item # | Product Name | Supplied |
|---|---|---|
| *30031748* | *PROIN® 25mg Chewable Tablets* | *60 ct. bottle* |
| *30031750* | *PROIN® 25mg Chewable Tablets* | *180 ct. bottle* |
| *30030748* | *PROIN® 50mg Chewable Tablets* | *60 ct. bottle* |
| *30030750* | *PROIN® 50mg Chewable Tablets* | *180 ct. bottle* |
| *30031548* | *PROIN® 75mg Chewable Tablets* | *60 ct. bottle* |
| *30031550* | *PROIN® 75mg Chewable Tablets* | *180 ct. bottle* |

**IMPORTANT SAFETY INFORMATION:** For oral use in dogs only. Not for human use. Keep out of reach of children. If accidentally ingested by humans, contact a physician immediately.

The most commonly reported side effects were vomiting, loss of appetite, diarrhea, excessive salivation, agitation, tiredness, vocalization, confusion, increased water consumption, weight loss, weakness, fever, panting, and reversible changes in skin color (flushing or bright pink). Abnormal gait, seizures or tremors, as well as liver enzyme elevations, kidney failure, blood in urine and urine retention have been reported. In some cases death, including euthanasia has been reported. Sudden death was sometimes preceded by vocalization or collapse.

Instances of dogs chewing through closed vials of PROIN® and eating the vial contents have been reported, in some cases resulting in overdose. Keep the product in a secured storage area out of the reach of pets in order to prevent accidental ingestion or overdose, as dogs may willingly consume more than the recommended dosage of PROIN® Chewable Tablets or PROIN ERTM tablets. Contact your veterinarian immediately if the dog ingests more tablets than prescribed or if other pets ingest PROIN Chewable tablets or PROIN ER tablets.

PROIN and PROIN ER may cause elevated blood pressure and should be used with caution in dogs with pre-existing heart disease, high blood pressure, liver disease, kidney insufficiency, diabetes, glaucoma, and other conditions associated with high blood pressure. Dogs may transition from PROIN Chewable Tablets to PROIN ER without a break in administration. However, do not alternate PROIN ER with PROIN Chewable Tablets because the effectiveness and safety of interchangeable use have not been evaluated.

The safe use of PROIN and PROIN ER in dogs used for breeding purposes, during pregnancy or in lactating bitches, has not been evaluated. Contact your veterinarian if you notice restlessness or irritability, loss of appetite, the incontinence persists or worsens, or any other unusual signs. See prescribing information for complete details regarding adverse events, warning and precautions or visit prnpharmacal.com.

# Neurology and Behavior


## Reconcile®
*(fluoxetine hydrochloride)*

**USES** *Reconcile® is an FDA-approved flavored, chewable tablet to treat separation anxiety in dogs in conjunction with a behavior modification plan.*

| Item # | Product Name | Supplied |
|---|---|---|
| 10034057 | Reconcile® 8mg Chewable Tablets | 30 ct. bottle |
| 10034157 | Reconcile® 16mg Chewable Tablets | 30 ct. bottle |
| 10034257 | Reconcile® 32mg Chewable Tablets | 30 ct. bottle |
| 10034357 | Reconcile® 64mg Chewable Tablets | 30 ct. bottle |

**IMPORTANT SAFETY INFORMATION:** The most common adverse events in decreasing order of reported frequency are: decreased appetite, depression/lethargy, shaking/shivering/tremor, vomiting, restlessness and anxiety, seizures, aggression, diarrhea, mydriasis, vocalization, weight loss, panting, confusion, incoordination, and hypersalivation. Reconcile chewable tablets are contraindicated for dogs with a history of seizures or when used with MAOIs. For product label, including complete safety information, see enclosed package insert.






## K•BroVet®
*Chewable Tablets and Oral Solutions*

**USES** *K•BroVet® is the only potassium bromide manufactured in a current Good Manufacturing Practices (cGMP) facility regulated by the FDA. K•BroVet is available in chewable, liver-flavored tablets and butterscotch-vanilla-flavored oral solutions, reducing the need for compounding.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30032248 | K•BroVet® 250mg Chewable Tablets | 60 ct. bottle |
| 30032148 | K•BroVet® 500mg Chewable Tablets | 60 ct. bottle |
| 30024503 | K•BroVet® Oral Solution | 2 oz. bottle |
| 30024507 | K•BroVet® Oral Solution | 10 oz. bottle |


## Zentrol®
*Chewable Tablets*

**USES** *Zentrol® Chewable Tablets are recommended for the management of stress-related behaviors in dogs. The scored, palatable, beef-flavored chewable tablet is easy to administer and demonstrates positive behavior effects in as few as 60 minutes.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100525816 | Zentrol® Chewable Tablets | 60 ct. bottle |


## CoproBan®
*Chews*

**USES** *CoproBan® Chews are formulated with MSG and cellulase to assist in the breakdown of fiber, rendering the taste and texture of the stool unpleasant to eat, helping manage coprophagia. Roast beef-flavored CoproBan tablets eliminate messy powders, helping make dosing easier.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30032562 | CoproBan® Chews | 20 ct. box |

# Parasite Control – Yard and Home


## Vet-Kem® Yard Spray

***permethrin***

**USES** *Kills mosquitoes, fleas, ticks, ants and over 40 other insects, including deer ticks that may cause Lyme disease. Treats up to 5,000 square feet of lawns, trees, shrubs, roses and other flowers.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100527195 | Vet-Kem® Yard Spray | 32 oz. hose-end sprayer |


## Vet-Kem® Home Spray

***(s)-methoprene/etofenprox/piperonyl butoxide***

**USES** *Targeted spray pattern provides good coverage of hard to reach cracks and crevices in apartments, homes, garages, bedrooms and attics. Kills fleas, ticks, cockroaches, ants, spiders, flies, mosquitoes, and other listed insects. Dual action – kills and prevents new infestations. Protects for up to 7 months.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100527067 | Vet-Kem® Home Spray | 24 oz. bottle |






## Vet-Kem® Carpet and Premise Spray

***(s)-methoprene/permethrin/phenothrin/n-octyl bicycloheptene dicarboximide/piperonyl butoxide***

**USES** *Delivering 100% knock down of adult fleas in 10 minutes. Use as a spot treatment on carpets, rugs, upholstery, drapes and other places where fleas may hide. Prevents reinfestation and flea build-up for 7 months. Treats up to 2,000 square feet.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100526870 | Vet-Kem® Carpet and Premise Spray | 16 oz. can |


## Vet-Kem® Fogger

***(s)-methoprene/permethrin***

**USES** *Kills fleas and ticks. Prevents flea reinfestation and flea build-up for up to 7 months. Leaves no lingering odor or stains, and each 3-ounce can treats up to 3,000 cubic feet.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100526871 | Vet-Kem® Fogger | 3 x 3 oz. cans |


## Mycodex® Plus Environmental Control™ Aerosol Household Spray

***linalool/n-octyl bicycloheptene dicarboximide/ pyriproxyfen/permethrin***

**USES** *Featuring the botanically derived insecticide Linalool, Mycodex® Plus Environmental Control™ Aerosol Household Spray kills all four stages of the flea: adults, eggs, pupae and larvae, and controls reinfestation for up to 210 days. Also kills ticks, roaches, ants, spiders, lice, crickets, centipedes, waterbugs, silverfish, and sowbugs.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100530868 | Mycodex® Plus Environmental Control™ Aerosol Household Spray | 16 oz. can |

# Parasite Control – Pet




## Vet-Kem® Flea & Tick Spot On® for Dogs

***(s)-methoprene/etofenprox/piperonyl butoxide***

**USES** *Vet-Kem® Flea & Tick Spot On® for Dogs starts killing fleas and ticks within 15 minutes. Dual protection kills and repel fleas and ticks (including Deer ticks that may carry Lyme disease). Also kills and repels mosquitoes (the major carrier of canine heartworm). It kills fleas, flea larvae, flea eggs, ticks, and mosquitoes on dogs and puppies 10 weeks of age or older. It provides flea, tick and mosquito protection for up to 30 days.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100528565 | Vet-Kem® Flea & Tick Spot On® for Dogs (Toy 6-12 lb.) | 3 pipettes x 1 box |
| 100528488 | Vet-Kem® Flea & Tick Spot On® for Dogs (Small 13-31 lb.) | 3 pipettes x 1 box |
| 100528487 | Vet-Kem® Flea & Tick Spot On® for Dogs (Medium 32-55 lb.) | 3 pipettes x 1 box |
| 100528489 | Vet-Kem® Flea & Tick Spot On® for Dogs (Large 56-80 lb.) | 3 pipettes x 1 box |
| 100528510 | Vet-Kem® Flea & Tick Spot On® for Dogs (X-Large 81 lb. and up) | 3 pipettes x 1 box |


## Vet-Kem® Flea and Tick Spot On® for Cats

***(s)-methoprene/etofenprox***

**USES** *Vet-Kem® Flea & Tick Spot On® for Cats starts killing fleas within 15 minutes. It provides 5 in 1 protection against fleas, flea larvae, flea eggs, Deer ticks, and mosquitoes on cats or kittens 12 weeks of age or older. It provides flea, Deer tick and mosquito protection for up to 30 days.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100528511 | Vet-Kem® Flea & Tick Spot On® for Cats (Large 5 lb. and up) | 3 pipettes x 1 box |



# Parasite Control – Pet

## Vet-Kem® Flea, Tick and Bot Spray

***(s)-methoprene/pyrethrins/piperonyl butoxide/n-octyl bicycloheptene dicarboximide***

**USES** *For use on dogs, puppies, cats, kittens, horses and ponies. Quick-acting formulation kills and repels fleas, lice, flies, mosquitoes and gnats. Kills and repels Deer ticks that may carry Lyme disease. Kills flea eggs and prevents bot fly eggs from hatching. May be reapplied weekly.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100527066 | Vet-Kem® Flea, Tick & Bot Spray | 16 oz. bottle |


## Vet-Kem® Flea and Tick Shampoo

***(s)-methoprene/pyrethrins/piperonyl butoxide***

**USES** *For cats, kittens, dogs and puppies, this shampoo has a sensitive skin formulation that contains soothing aloe, lanolin and oatmeal. It kills fleas, ticks and lice on contact, and prevents flea eggs from hatching for up to 28 days.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100527065 | Vet-Kem® Flea and Tick Shampoo for Dogs & Cats | 12 oz. bottle |
| 100531084 | Vet-Kem® Flea and Tick Shampoo for Dogs & Cats | 1 gal. bottle |


## Mycodex® Flea & Tick Shampoo P³

***pyrethrins/piperonyl butoxide***

**USES** *Specially formulated for dogs, cats, puppies, and kittens 12 weeks of age and older, Mycodex® Flea & Tick Shampoo P³ contains 0.15% pyrethrin to kill adult fleas and ticks on contact. The sensitive skin formulation moisturizes coat and removes loose dandruff, dirt, and scales.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100531072 | Mycodex® Flea & Tick Shampoo P³ | 6 oz. bottle |
| 100531057 | Mycodex® Flea & Tick Shampoo P³ | 12 oz. bottle |
| 100531058 | Mycodex® Flea & Tick Shampoo P³ | 1 gal. bottle |


## Mycodex All-In-One® Flea & Tick Spray

***(s)-methoprene/pyrethrins/piperonyl butoxide/n-octyl bicycloheptene dicarboximide***

**USES** *Mycodex All-In-One® Flea & Tick Spray is a fast-acting formulation that kills and repels lice, flies, mosquitos, gnats, fleas, and ticks, including those that carry Lyme disease. For dogs, cats, puppies and kittens 12 weeks of age and older, a single treatment works for two months to keep flea eggs from hatching.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100531070 | Mycodex All-In-One® Flea & Tick Spray | 16 oz. bottle |

# Skin and Coat


## CAMEO®

*Otic Ointment*

**USES** *CAMEO® Otic Ointment is formulated to help maintain a healthy ear environment in dogs. Single-use tubes and once-a-week dosing improve client compliance, and CAMEO contains no steroids or antibiotics.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30013229 | CAMEO® Otic Ointment 8 pk. | 8 x 2.5g tubes |






## OPTIMA 365™

*Nutritional Liquid*

**USES** *OPTIMA 365™ Liquid for Dogs and OPTIMA 365™ Liquid for Cats is an optimal combination of vitamins, minerals, fatty acids, antioxidants and amino acids that promote a healthy skin and coat. The formulation of these ingredients in a flavored, oral solution support the reduction of non-seasonal shedding.*

| Item # | Product Name | Supplied |
|---|---|---|
| 3005441 | OPTIMA 365™ Liquid for Dogs | 16 oz. bottle |
| 3005442 | OPTIMA 365™ Liquid for Cats | 16 oz. bottle |
| 3005443 | OPTIMA 365™ Liquid for Dogs | 1 gal. bottle with pump dispenser |


## Hexa-Caine™

*Topical Anti-Itch Spray*

**USES** *Hexa-Caine™ Spray is a clinically developed, veterinarian-tested topical anesthetic spray (with 2.46% lidocaine HCl) that quickly soothes minor skin problems. Contains bitter-tasting flavoring agent Bitrex® to stop fur licking and wound biting. Should not be used on open wounds.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30023604 | Hexa-Caine™ Spray | 4 oz. spray bottle |


## Vetadryl®

*Diphenhydramine HCl Tablets*

**USES** *Vetadryl® is a chicken-liver flavored diphenhydramine (DPH) HCl tablet for anti-histamine relief manufactured specifically for pets.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30032945 | Vetadryl® 10mg | 250 ct. bottle |
| 30033045 | Vetadryl® 30mg | 250 ct. bottle |
| 30032957 | Vetadryl® 10mg | 30 ct. bottle |
| 30033057 | Vetadryl® 30mg | 30 ct. bottle |

# Nutritional Therapeutics

## Duralactin®

### *Canine Chewable Tablets/Canine Soft Chews*

**USES** *Formulated to help manage inflammation and support normal activity and wellness in dogs and puppies, Duralactin® Canine Chewable Tablets and Duralactin® Canine Soft Chews contain MicroLactin®, an exclusive dried milk protein concentrate derived from hyperimmunized cows.*

| Item # | Product Name | Supplied |
|---|---|---|
| 3002932 | Duralactin® Canine Chewable Tablets | 60 ct. bottle |
| 3004948 | Duralactin® Canine Chewable Tablets | 180 ct. bottle |
| 100521847 | Duralactin® Canine Soft Chews | 60 ct. bottle |
| 100521848 | Duralactin® Canine Soft Chews | 90 ct. bottle |

## Duralactin®

### *Canine Joint Plus Soft Chews*

**USES** *Recommended to help maintain healthy cartilage and joint function while managing inflammation, Duralactin® Canine Joint Plus Soft Chews contain MicroLactin®, an exclusive dried milk protein concentrate derived from hyperimmunized cows, Glucosamine HCl, MSM, Omega-3 (DHA), and Omega-6 (EPA) Fatty Acids, Zinc, Manganese and Vitamin E.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100522704 | Duralactin® Canine Joint Plus Soft Chews | 60 ct. bottle |
| 100522703 | Duralactin® Canine Joint Plus Soft Chews | 90 ct. bottle |



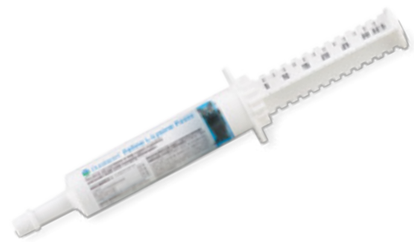


## Duralactin®

### *Feline + Fatty Acids Soft Chews*

**USES** *Formulated to help support healthy skin and manage inflammation, Duralactin® Feline + Fatty Acids Soft Chews contain MicroLactin®, an exclusive dried milk protein concentrate derived from hyperimmunized cows, Omega-3 (DHA), and Omega-6 (EPA) Fatty Acids.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100521850 | Duralactin® Feline + Fatty Acids Soft Chews | 60 ct. bottle |



## Duralactin®

### *Feline L-lysine Paste*

**USES** *Formulated to help support respiratory and ocular health while helping to manage inflammation. Duralactin® Feline L-lysine Paste contains MicroLactin®, an exclusive dried milk protein concentrate derived from hyperimmunized cows, Omega-3 (DHA), and Omega-6 (EPA) Fatty Acid, as well as, L-lysine in a dial-a-dose syringe for ease of use.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100504080 | Duralactin® Feline L-lysine Paste | 32.5mL syringe |

## Duralactin®

### *Feline Capsules*

**USES** *Formulated to help manage inflammation and support normal activity and wellness, Duralactin® Feline Capsules contain MicroLactin®, an exclusive dried milk protein concentrate derived from hyperimmunized cows.*

| Item # | Product Name | Supplied |
|---|---|---|
| 3003829 | Duralactin® Feline Capsules | 60 ct. bottle |

## ProZyme®

### *Nutritional Supplement*

**USES** *ProZyme® improves nutrient absorption through a combination of plant-derived digestive enzymes in a palatable powder form. ProZyme can aid in the support of food breakdown and reinforce a pet's own small intestine digestive enzymes.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30042384 | ProZyme® Powder 85g | 3 oz. bottle |
| 30042385 | ProZyme® Powder 200g | 7 oz. bottle |
| 30042386 | ProZyme® Powder 454g | 1 lb. bottle |

# Critical Care and Surgical Support


## STAT®

### *Concentrated, High-Calorie Liquid Supplement*

**USES** *STAT® is a high-calorie (150 calories per ounce) liquid dietary supplement that can help restore hydration and maintain nutrient balances in animals with additional nutritional needs or that may be under stress. STAT can be top-dressed over the animal's normal diet or administered "as is" to animals with decreased appetite.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30022409 | STAT® | 16 oz. bottle |


## Liqui·Tinic® 4x

### *Flavored Vitamin and Iron Supplement*

**USES** *Liqui•Tinic® 4x Concentrate is an oral-use liquid supplement that supplies iron and B-complex vitamins in a flavored, easy-to-use form.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30022003 | Liqui•Tinic® 4x | 2 oz. bottle |



# Critical Care and Surgical Support


## Calsorb™

### *Oral Calcium Supplement*

**USES** *Calsorb™ is a readily absorbing, gel-based oral calcium supplement that provides an alternative to support healthy calcium levels in dogs.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30010835 | Calsorb™ | 12mL syringe |


## GastroMate®

### *Canine IgY Plus Gel*

**USES** *GastroMate® contains egg yolk anti-bodies (IgY Immunoglobulins), direct fed microbials, antioxidants, and vitamins. The flavored gel provides digestive support for puppies and dogs, aids in healthy intestinal function and is an excellent source of digestible proteins and fats.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30012538 | GastroMate® Canine IgY | 15cc dial-a-dose syringe |


## Endosorb®

### *Adsorbent Anti-Diarrheal*

**USES** *Endosorb® products are formulated with a proven attapulgite that can help improve the stool consistency in animals. A low-cost treatment that supports intestinal function, Endosorb is formulated to stabilize stool viscosity and soothe the gastrointestinal tract. Suspension formulation is flavored and sweetened for easier dosing.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30030251 | Endosorb® Tablets | 500 ct. bottle |
| 30021704 | Endosorb® Suspension | 4 oz. bottle |

⚠ **WARNING:** This product can expose you to crystalline silica, which when airborne particles of respirable size are inhaled, is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov


## Pet-Ema® and Feline Pet-Ema®

### *Single Use Enema*

**USES** *Pet-Ema® is an aid in maintaining healthy lower bowel function.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30022835 | Pet-Ema® | 12mL syringe |
| 30021934 | Feline Pet-Ema® | 6mL syringe |

# Wound Care and Closure


## Collasate® Family

***Postoperative Topical Dressing***

**USES** *The Collasate® family of products are manufactured with a medical-grade hydrolysate of Type I collagen in a form immediately available to the body. Collasate helps restore and maintain a healthy wound environment optimal for healing. Can also be used on birds and reptiles.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30012173 | Collasate® | 7g tube |
| 30024402 | Collasate® Spray | 1 oz. spray bottle |
| 30013173 | Collasate® SILVER | 7g tube |






## Monomend® ST

***Absorbable Sutures***

**USES** *Monomend® ST is an undyed, short-term, synthetic absorbable suture. Monomend® ST is a terpolymer of glycolide, trimethylene carbonate and caprolactone. Monomend® ST sutures provide 6-7 days of wound support and is completely absorbed in 56 days (0% tensile strength between 14-21 days). Monomend® ST sutures are indicated for mucosal, facial, dermal, and urinary bladder surgeries.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100523604 | Monomend® ST RST-VR490-1 (5-0) DSMP11 (3/8 RC) 18″ | 12 x 1 box |
| 100523605 | Monomend® ST RST-VR463-1 (5-0) DSMP13 (3/8 RC) 18″ | 12 x 1 box |
| 100523606 | Monomend® ST RST-VR494-1 (4-0) DSMP13 (3/8 RC) 18″ | 12 x 1 box |
| 100523607 | Monomend® ST RST-VR497-1 (3-0) DSMP19 (3/8 RC) 18″ | 12 x 1 box |
| 100523608 | Monomend® ST RST-VR214-1 (4-0) HR17 (½ TP) 18″ | 12 x 1 box |


## Monomend® MT

***Absorbable Sutures***

**USES** *Monomend® MT is a violet monofilament mid-term synthetic absorbable surture. Monomend® MT is a terpolymer of glycolide, caprolactone, and trimetheylene carbonate.Monomend® MT sutures provide 14 days of wound support and is completely absorbed in 60-90 days (0% initial tensile strength after 28 days). Monomend® MT sutures are indicated for general soft tissue surgery.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100523564 | Monomend® MT RM-Y922-1 (4-0) DS19 (3/8 RC) 36″ | 12 x 1 box |
| 100523565 | Monomend® MT RM-Y923-1 (3-0) DS19 (3/8 RC) 36″ | 12 x 1 box |
| 100523566 | Monomend® MT RM-Y942-1 (3-0) DS24 (3/8 RC) 36″ | 12 x 1 box |
| 100523567 | Monomend® MT RM-Y943-1 (2-0) DS24 (3/8 RC) 36″ | 12 x 1 box |
| 100523569 | Monomend® MT RM-Y966-1 (2-0) HS37s (½ RC) 36″ | 12 x 1 box |
| 100523568 | Monomend® MT RM-Y987-1 (0) DS30 (3/8 RC) 36″ | 12 x 1 box |
| 100523570 | Monomend® MT RM-Y967-1 (0) HS37s (½ RC) 36″ | 12 x 1 box |
| 100523571 | Monomend® MT RM-Y968-1 (1) HS37s (½ RC) 36″ | 12 x 1 box |
| 100523545 | Monomend® MT RM-Y463-1 (5-0) DSMP13 (3/8 RC) 18″ | 12 x 1 box |
| 100523563 | Monomend® MT RM-Y844-1 (5-0) DSMP16 (3/8 RC) 18″ | 12 x 1 box |
| 100523562 | Monomend® MT RM-Y464-1 (4-0) DSMP13 (3/8 RC) 18″ | 12 x 1 box |
| 100523572 | Monomend® MT RM-Y303-1 (5-0) HR17 (½ TP) 18″ | 12 x 1 box |
| 100523573 | Monomend® MT RM-Y304-1 (4-0) HR17 (½ TP) 36″ | 12 x 1 box |
| 100523574 | Monomend® MT RM-Y315-1 (4-0) HR26 (½ TP) 36″ | 12 x 1 box |
| 100523575 | Monomend® MT RM-Y316-1 (3-0) HR26 (½ TP) 36″ | 12 x 1 box |
| 100523577 | Monomend® MT RM-Y761-1 (3-0) HR26s (½ TP) 36″ | 12 x 1 box |
| 100523579 | Monomend® MT RM-Y344-1 (3-0) HR37s (½ TP) 36″ | 12 x 1 box |
| 100523576 | Monomend® MT RM-Y317-1 (2-0) HR26 (½ TP) 36″ | 12 x 1 box |
| 100523578 | Monomend® MT RM-Y762-1 (2-0) HR26s (½ TP) 36″ | 12 x 1 box |
| 100523580 | Monomend® MT RM-Y345-1 (2-0) HR37s (½ TP) 36″ | 12 x 1 box |
| 100523581 | Monomend® MT RM-Y346-1 (0) HR37s (½ TP) 36″ | 12 x 1 box |
| 100523582 | Monomend® MT RM-Y347-1 (1) HR37s (½ TP) 36″ | 12 x 1 box |

## Monomend® MaX

### *Absorbable Sutures*

**USES** *Monomend® MaX is a violet, monofilament long-term, synthetic polydioxanone suture ideal for cases where extended wound support of more than 4 weeks is desired. Monomend® Max provides wound support for 35 days and offers complete absorption in 180-210 days (0% tensile strength at 70 days). Monomend® MaX is indicated for subcuticular and general closures as well as soft tissue, cardiovascular, and orthopedic surgery.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100523583 | Monomend® MaX RX-Z421-1 (5-0) DS19 (3/8 RC) 27″ | 12 x 1 box |
| 100523584 | Monomend® MaX RX-Z397-1 (4-0) DS19 (3/8 RC) 27″ | 12 x 1 box |
| 100523585 | Monomend® MaX RX-Z398-1 (3-0) DS19 (3/8 RC) 27″ | 12 x 1 box |
| 100523586 | Monomend® MaX RX-Z452-1 (3-0) DS24 (3/8 RC) 27″ | 12 x 1 box |
| 100523587 | Monomend® MaX RX-Z451-1 (2-0) DS24 (3/8 RC) 27″ | 12 x 1 box |
| 100523588 | Monomend® MaX RX-Z969-1 (2-0) HS26s (½ RC) 27″ | 12 x 1 box |
| 100523590 | Monomend® MaX RX-Z466-1 (2-0) HS37s (½ RC) 27″ | 12 x 1 box |
| 100523589 | Monomend® MaX RX-Z970-1 (0) HS26s (½ RC) 27″ | 12 x 1 box |
| 100523591 | Monomend® MaX RX-Z467-1 (0) HS37s (½ RC) 27″ | 12 x 1 box |
| 100523592 | Monomend® MaX RX-Z310-1 (4-0) HR22 (½ TP) 27″ | 12 x 1 box |
| 100523594 | Monomend® MaX RX-Z315-1 (4-0) HR26 (½ TP) 27″ | 12 x 1 box |
| 100523593 | Monomend® MaX RX-Z311-1 (3-0) HR22 (½ TP) 27″ | 12 x 1 box |
| 100523595 | Monomend® MaX RX-Z316-1 (3-0) HR26 (½ TP) 27″ | 12 x 1 box |
| 100523597 | Monomend® MaX RX-Z332-1 (3-0) HR26s (½ TP) 27″ | 12 x 1 box |
| 100523596 | Monomend® MaX RX-Z317-1 (2-0) HR26 (½ TP) 27″ | 12 x 1 box |
| 100523598 | Monomend® MaX RX-Z333-1 (2-0) HR26s (½ TP) 27″ | 12 x 1 box |
| 100523600 | Monomend® MaX RX-Z339-1 (2-0) HR37s (½ TP) 27″ | 12 x 1 box |
| 100523599 | Monomend® MaX RX-Z334-1 (0) HR26s (½ TP) 27″ | 12 x 1 box |
| 100523601 | Monomend® MaX RX-Z340-1 (0) HR37s (½ TP) 27″ | 12 x 1 box |
| 100523602 | Monomend® MaX RX-Z341-1 (1) HR37s (½ TP) 27″ | 12 x 1 box |
| 100523603 | Monomend® MaX RX-Z371-1 (1) HR48 (½ TP) 27″ | 12 x 1 box |

## Polymend® MT

### *Absorbable Sutures*

**USES** *Polymend® MT is a violet braided, mid-term synthetic PGLA (Polyglactin 910) suture that provides easy handling and excellent knot security. Polymend® MT sutures provide wound support for 21 days (0% initial tensile strength after 35 days) and offers complete mass absorption in 56-70 days.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100510826 | Polymend® MT B-J421-1 (5-0) DS19 (3/8 RC) 27″ | 12 x 1 box |
| 100510853 | Polymend® MT B-J397-1 (4-0) DS19 (3/8 RC) 27″ | 12 x 1 box |
| 100510854 | Polymend® MT B-J398-1 (3-0) DS19 (3/8 RC) 27″ | 12 x 1 box |
| 100510858 | Polymend® MT B-J452-1 (3-0) DS24 (3/8 RC) 27″ | 12 x 1 box |
| 100510859 | Polymend® MT B-J453-1 (2-0) DS24 (3/8 RC) 27″ | 12 x 1 box |
| 100510855 | Polymend® MT B-J466-1 (2-0) HS37s (½ RC) 27″ | 12 x 1 box |
| 100510856 | Polymend® MT B-J467-1 (0) HS37s (½ RC) 27″ | 12 x 1 box |
| 100510857 | Polymend® MT B-J474-1 (1) HS37s (½ RC) 27″ | 12 x 1 box |
| 100523629 | Polymend® MT B-J303-1 (5-0) HR17 (½ TP) 27″ | 12 x 1 box |
| 100510827 | Polymend® MT B-J315-1 (4-0) HR26 (½ TP) 27″ | 12 x 1 box |
| 100510828 | Polymend® MT B-J316-1 (3-0) HR26 (½ TP) 27″ | 12 x 1 box |
| 100510850 | Polymend® MT B-J332-1 (3-0) HR26s (½ TP) 27″ | 12 x 1 box |
| 100510829 | Polymend® MT B-317-1 (2-0) HR26 (½ TP) 27″ | 12 x 1 box |
| 100510851 | Polymend® MT B-J333-1 (2-0) HR26s (½ TP) 27″ | 12 x 1 box |
| 100510852 | Polymend® MT B-J340-1 (0) HR37s (½ TP) 27″ | 12 x 1 box |



Wound Care and Closure

## NY-STĀ®

### *Non-Absorbable Sutures*

**USES** *NY-STĀ® is a non-absorbable nylon monofilament black suture intended for use in general soft tissue approximation, including use in catheter fixation and skin closure.*

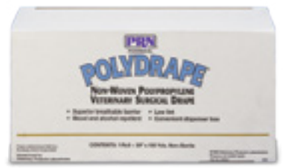
| Item # | Product Name | Supplied |
|---|---|---|
| 30020 | NY-STĀ® N-662-1 (4-0) DS19 (3/8 RC) 18″ | 12 x 1 box |
| 30021 | NY-STĀ® N-663-1 (3-0) DS24 (3/8 RC) 18″ | 12 x 1 box |
| 100503730 | NY-STĀ® N-669-1 (3-0) DS24 (3/8 RC) 30″ | 12 x 1 box |
| 30022 | NY-STĀ® N-664-1 (2-0) DS24 (3/8 RC) 18″ | 12 x 1 box |
| 100503729 | NY-STĀ® N-66430-1 (2-0) DS24 (3/8 RC) 30″ | 12 x 1 box |
| 100523628 | NY-STĀ® N-628-1 (2-0) GS60 (SC) 30″ | 12 x 1 box |

## PRO-STĀ FLX™

### *Non-Absorbable Sutures*

**USES** *PRO-STĀ FLX™ is a non-absorbable, monofilament blue 95% polypropylene and 5% polyethylene co-polymer for increased handling and facilitation of knot-tying.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100527367 | PRO-STĀ FLX™ P-8683 (4-0) DS19 (3/8 RC) 18″ | 12 x 1 box |
| 100527368 | PRO-STĀ FLX™ P-8684 (3-0) DS24 (3/8 RC) 18″ | 12 x 1 box |
| 100527369 | PRO-STĀ FLX™ P-8685 (2-0) DS24 (3/8 RC) 18″ | 12 x 1 box |
| 100527380 | PRO-STĀ FLX™ P-8424 (0) HR37s (1/2 TP) 30″ | 12 x 1 box |
| 100527381 | PRO-STĀ FLX™ P-8140 (1) HS40 (1/2 RC) 30″ | 12 x 1 box |




## Polydrape™

### *Surgical Drape*

**USES** *An advanced 3-layer veterinary surgical drape that has autoclavable properties (do not "flash" autoclave), Polydrape™ Surgical Drape has excellent breathability. The 3-layer structure readily allows gases and vapors to pass through. It is alcohol repellent and acts as a barrier to blood with a low lint design that helps reduce surgical field contamination.*

| Item # | Product Name | Supplied |
|---|---|---|
| 90300 | Polydrape™ Surgical Drape | 42 inches x 100 yards |

# Medical Devices



## B. Braun-Aesculap® Surgical

### *Blades, Handles and Scalpels*

**USES** *The difference is not always obvious, but you know it when you feel it. Aesculap scalpel blades are made from extra-hard carbon steel with a high cutting quality. Thanks to manufacturing techniques based on high-tech craftsmanship, know-how, experience and care of Aesculap's surgical technicians, you can experience the Aesculap quality for yourself.*

| Item # | Product Name | Supplied |
|---|---|---|
| ***SURGICAL SCALPELS*** | | |
| BA210 | Carbon Steel Scalpels, Sterile; size #10 | 10/box |
| BA211 | Carbon Steel Scalpels, Sterile; size #11 | 10/box |
| BA212 | Carbon Steel Scalpels, Sterile; size #12 | 10/box |
| BA215 | Carbon Steel Scalpels, Sterile; size #15 | 10/box |
| BA220 | Carbon Steel Scalpels, Sterile; size #20 | 10/box |
| BA221 | Carbon Steel Scalpels, Sterile; size #21 | 10/box |
| BA222 | Carbon Steel Scalpels, Sterile; size #22 | 10/box |
| BA810SU | Carbon Steel Safety Scalpels, Sterile; size #10 | 10/box |
| BA815SU | Carbon Steel Safety Scalpels, Sterile; size #15 | 10/box |
| ***SURGICAL HANDLES*** | | |
| BB073R | Scalpel Handle; size 3 – 125mm | 1/pack |
| BB074R | Scalpel Handle w/ measure; size 3 – 125mm | 1/pack |
| BB075R | Scalpel Handle; size 3L – 210mm | 1/pack |
| BB084R | Scalpel Handle; size 4 – 135mm | 1/pack |
| BB080R | Scalpel Handle; size 4 straight – 225mm | 1/pack |
| BB046R | Scalpel Handle; round (for Micro Blades) – 135mm | 1/pack |
| ***SURGICAL BLADES*** | | |
| BB510 | Carbon Steel Scalpel Blades, Sterile; size #10 | 100/box |
| BB511 | Carbon Steel Scalpel Blades, Sterile; size #11 | 100/box |
| BB512 | Carbon Steel Scalpel Blades, Sterile; size #12 | 100/box |
| BB515 | Carbon Steel Scalpel Blades, Sterile; size #15 | 100/box |
| BB515-C | Carbon Steel Scalpel Blades, Sterile; size #15-C | 100/box |
| BB520 | Carbon Steel Scalpel Blades, Sterile; size #20 | 100/box |
| BB521 | Carbon Steel Scalpel Blades, Sterile; size #21 | 100/box |
| BB522 | Carbon Steel Scalpel Blades, Sterile; size #22 | 100/box |
| BB523 | Carbon Steel Scalpel Blades, Sterile; size #23 | 100/box |
| BB524 | Carbon Steel Scalpel Blades, Sterile; size #24 | 100/box |
| BB525 | Carbon Steel Scalpel Blades, Sterile; size #25 | 100/box |
| BB364R | Micro-Scalpel Blades, Sterile; round tip | 10/pack |
| BB365R | Micro-Scalpel Blades, Sterile; size mini #11 | 10/pack |
| BB367R | Micro-Scalpel Blades, Sterile; size mini #15 | 10/pack |
| BB369R | Micro-Scalpel Blades, Sterile; double-round tip | 1/pack |

## Argon Medical Intracath™

### *Catheters*

**USES** *For use in large dogs, Argon Medical Intracath™ Catheters are made of Vialon™ Biomaterial with unique, self-contained, through-the-needle introducer system and wire stylet, allowing for rapid catheterization. The removable sheath minimizes touch contamination, and the stainless steel stylet assists in advancing catheter into the vein.*

| Item # | Product Name | Supplied |
|---|---|---|
| 384900 | Intracath™ Catheter, 16 G x 8.00 in. | 50/box |
| 384901 | Intracath™ Catheter, 19 G x 8.00 in. | 50/box |
| 384902 | Intracath™ Catheter, 22 G x 8.00 in. | 50/box |
| 384903 | Intracath™ Catheter, 16 G x 12.00 in. | 50/box |
| 384904 | Intracath™ Catheter, 19 G x 12.00 in. | 50/box |
| 384905 | Intracath™ Catheter, 16 G x 24.00 in. | 50/box |
| 384906 | Intracath™ Catheter, 19 G x 24.00 in. | 50/box |

## Pet Pillers

### *Pill Dispenser*

**USES** *The Pet Pillers Pill Dispenser safely administers pills to pets with a soft tip to protect from injury, and allows for capsules and various size tablets.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30051399 | Pet Piller | 12 x 1 piller |

# Livestock Health

## Safe-Flow

*Oral Gel Dispenser*

**USES** *The Safe-Flow Oral Gel Dispenser is a durable, easy-to-use dispenser that delivers 300mL of oral gel.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30052299 | Safe-Flow Dispenser | 12 x 1 dispenser |


## Hi-Energy Supplement®

*Nutritional Supplement*

**USES** *Hi-Energy Supplement® is a nutritional supplement with amino acids, B-complex vitamins, poultry liver, and iron, and formulated with propylene glycol to supply additional energy support to growing or stressed livestock.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30010236 | High Energy Supplement® | 300mL tube |


## Magna Gel®

*Nutritional Supplement*

**USES** *Magna Gel® provides an oral nutrition supplement to support cattle suffering from conditions related to magnesium deficiency.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30010336 | Magna Gel® | 300mL tube |






## High Potency Calcium Gel®

*Nutritional Supplement*

**USES** *High Potency Calcium Gel® contains calcium chloride specifically formulated in a quickly absorbed gel based to support livestock that may have additional dietary calcium needs.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30010936 | HP Calcium Gel® | 300mL tube |


## High Potency CMPK Drench Plus™ and Slow Release Bolus

*Nutritional Supplement*

**USES** *High Potency CMPK Drench Plus™ and Slow Release CMPK Bolus provide rapidly absorbing calcium, magnesium, potassium, and phosphates, as well as vitamin E and $D_3$ for improved absorption for livestock with nutritional deficiencies or additional dietary needs due to stress.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30020122 | CMPK Drench Plus™ | 1 gal. bottle |
| 30000547 | Slow Release Bolus | 50 ct. jar |


## Endosorb®

*Adsorbent Anti-Diarrheal*

**USES** *Endosorb® products are formulated with a proven attapulgite that can help improve the stool consistency in animals. A low-cost treatment that supports intestinal function, Endosorb is formulated to stabilize stool viscosity and soothe the gastrointestinal tract. The safety of Endosorb in dairy cattle has not been evaluated.*

| Item # | Product Name | Supplied |
|---|---|---|
| 30001347 | Endosorb® Bolus | 50 ct. jar |

⚠**WARNING:** This product can expose you to crystalline silica, which when airborne particles of respirable size are inhaled, is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov

## Vet-Kem® Paramite® Insecticidal Spray & Backrubber

*phosmet*

**USES** *Paramite® L.A. Insecticidal Spray & Backrubber for Cattle and Swine is a liquid concentrate that when properly diluted can be used as a spray on cattle or swine, or in cattle backrubbers. Paramite L.A. controls horn flies, lice, sarcoptic mange and ticks on cattle, and lice and sarcoptic mange on swine.*

| Item # | Product Name | Supplied |
|---|---|---|
| 100531083 | Paramite® L.A. Insecticidal Spray & Backrubber for Cattle & Swine | 32 oz. bottle |

# Equine Health


## ReBalance®

***(Sulfadiazine/Pyrimethamine Oral Suspension)***

**INDICATIONS** *ReBalance® (Sulfadiazine/Pyrimethamine Oral Suspension) Antiprotozoal oral suspension, when administered under labeled conditions, is an FDA-approved, safe and effective treatment for horses with equine protozoal myeloencephalitis (EPM) caused by* Sarcocystis neurona.

| Item # | Product Name | Supplied |
|---|---|---|
| *30024711* | *ReBalance®* | *1 qt. bottle* |

**IMPORTANT SAFETY INFORMATION:** For use in horses only. Do not use in horses intended for human consumption. Not for human use. Keep out of the reach of children. Prior to treatment with ReBalance Antiprotozoal Oral Suspension, EPM should be distinguished from other diseases that may cause ataxia in horses. Injuries or lameness may also complicate the evaluation of an animal with EPM. In most instances, ataxia due to EPM is asymmetrical and affects the front and/or the hind limbs. Treatment may cause generalized bone marrow suppression, anemia, leukopenia, neutropenia, and thrombocytopenia. A complete blood count (CBC) should be performed monthly to monitor horses for development of these conditions. The administration of the drug may need to be discontinued and/or treatments for bone marrow suppression initiated. Other, less frequent side effects included decreased appetite, loose stools, and mild colic. In most cases, the gastrointestinal signs were self-limiting and did not require discontinuation of treatment.

Worsened neurologic deficits (treatment crisis) may be observed during a period beginning with the first few days of treatment with ReBalance and ranging out to 5 weeks. This neurologic deficit exacerbation may be the result of an inflammatory reaction to the dying parasites in the CNS tissue. The safe use of ReBalance Antiprotozoal Oral Suspension in horses used for breeding purposes, during pregnancy, or in lactating mares has not been evaluated. The safety of ReBalance with concomitant therapies in horses has not been evaluated. ReBalance is not for use in horses with known hypersensitivity to sulfonamide drugs or Pyrimethamine. Refer to the prescribing information for complete details or visit prnpharmacal.com/rebalance.


## Liqui·Tinic® 4x

***Flavored Vitamin and Iron Supplement***

**USES** *Liqui•Tinic® 4x Concentrate is an oral-use liquid supplement that supplies iron and B-complex vitamins in a flavored, easy-to-use form.*

| Item # | Product Name | Supplied |
|---|---|---|
| *30022022* | *Liqui•Tinic® 4x* | *1 gal. bottle* |


## Vet-Kem® Clear Fly Repellent Ointment

***piperonyl butoxide/pyrethrins/di-n-propyl isocinchomeronate***

**USES** *For use on horses, ponies, and dogs, Vet-Kem® Clear Fly Repellent Ointment repels houseflies, stable flies, face flies, and horn flies.*

| Item # | Product Name | Supplied |
|---|---|---|
| *100531071* | *Vet-Kem® Clear Fly Repellent Ointment* | *2 oz. jar* |






## Duralactin®

***Equine Pellets***

**USES** *Duralactin Equine Pellets contina MicroLactin, an exclusive dried milk protein concentrate derived from hyperimmunized cows to help manage inflammation and support normal activity and wellness.*

| Item # | Product Name | Supplied |
|---|---|---|
| *100523768* | *Duralactin® Equine Pellets* | *1.875 lb. bag* |


## Duralactin®

***Equine Joint Plus Pellets***

**USES** *Duralactin® Equine Joint Plus Pellets contain MicroLactin®, an exclusive dried milk protein concentrate derived from hyperimmunized cows, plus Glucosamine HCl, Chondroitin, and Vitamin C to help manage inflammation and support joint health and function.*

| Item # | Product Name | Supplied |
|---|---|---|
| *100523767* | *Duralactin® Equine Joint Plus Pellets* | *3.75 lb. bag* |


## Endosorb®

***Adsorbent Anti-Diarrheal***

**USES** *Endosorb® products are formulated with a proven attapulgite that can help improve the stool consistency in animals. A low-cost treatment that supports intestinal function, Endosorb is formulated to stabilize stool viscosity and soothe the gastrointestinal tract. Suspension formulation is flavored and sweetened for easier dosing. Suspension formulation should not be used on cats.*

| Item # | Product Name | Supplied |
|---|---|---|
| *30021722* | *Endosorb® Suspension* | *1 gal. bottle* |

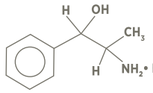
# PROIN ER™

## *(phenylpropanolamine hydrochloride extended-release tablets)*

For oral use in dogs only

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION:** PROIN ER (phenylpropanolamine hydrochloride extended-release tablets) is a sympathomimetic amine closely related to ephedrine. Phenylpropanolamine hydrochloride (PPA) is the nonproprietary designation for benzenemethanol, a-(1-aminoethyl)-hydrochloride, (R*, S*)-, (±). The empirical formula is $C_9H_{13}NO{\cdot}HCl$ and the molecular weight is 187.67. It is a white crystalline compound having a slight aromatic odor. PPA is freely soluble in water and alcohol but is practically insoluble in ether, benzene and chloroform. The chemical structure of phenylpropanolamine hydrochloride is:




**INDICATION:** For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

**DOSAGE AND ADMINISTRATION:** The recommended dosage is 2 to 4 mg/kg (0.9 to 1.8 mg/lb) of body weight once daily according to Table 1 below. Administer PROIN ER with food (see **Clinical Pharmacology**). **Do not split or crush tablets**.

Dogs weighing less than 10 pounds cannot be safely dosed because tablet administration would result in a dose over 4 mg/kg.

**Table 1. Dose Administration[a]**

| Body weight in pounds | PROIN ER |
|---|---|
| 10-20 | 18 mg |
| 21-40 | 38 mg |
| 41-80 | 74 mg |
| 81-125[b] | 145 mg |

[a]Body weight should be rounded to the nearest pound.

[b]Dogs exceeding 125 lbs should receive the appropriate combination of tablets to achieve the recommended dosage.

Dogs may transition from PROIN® Chewable Tablets to PROIN ER without a break in administration. However, do not alternate PROIN ER with PROIN Chewable Tablets because the effectiveness and safety of interchangeable use have not been evaluated.

**WARNINGS:** Not for human use. Keep out of reach of children. Consult a physician in case of accidental ingestion by humans.

Keep PROIN ER in a secured location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

**PRECAUTIONS:** Proin ER may mask signs of incontinence due to urinary tract infection. PROIN ER is not effective in dogs with incontinence due to neurologic disease or malformations.

PROIN ER may cause hypertension; therefore, use with caution in dogs with pre-existing heart disease, hypertension, liver disease, kidney insufficiency, diabetes, glaucoma, and conditions with a predilection for hypertension.

Use with caution in dogs receiving sympathomimetic drugs, tricyclic antidepressants, or monoamine oxidase inhibitors as increased toxicity may result. Use with caution in dogs administered halogenated gaseous anesthetics as this may increase the risk of cardiac arrhythmias.

A laboratory study on human blood revealed that phenylpropanolamine (PPA) used in conjunction with aspirin may potentiate decreased platelet aggregation.[1]

PROIN ER may cause increased thirst; therefore, provide dogs with ample fresh water.

The safe use of PROIN ER has not been evaluated in dogs that are intended for breeding, or that are pregnant or lactating.

**ADVERSE REACTIONS:** Adverse Reactions are listed below for both PROIN ER (NADA Number 141-517) and PROIN Chewable Tablets (NADA 141-324). PROIN ER (NADA 141-517 )

In the open-label clinical study involving 119 dogs administered PROIN ER once a day for 180 days, the following adverse reactions were observed.

**Table 2. Number and percentage of dogs with adverse reactions in the 180-day open-label clinical study for PROIN ER**

| Adverse Reactions | Total N=119 |
|---|---|
| Emesis | 39 (32.8%) |
| Body weight loss (≥5%) | 34 (28.6%) |
| Hypertension (≥160 mmHg) developed during study[a] | 15 (12.6%) |
| Diarrhea | 20 (16.8%) |
| Proteinuria | 16 (13.4%) |
| Tachycardia (≥160 bpm) | 11 (9.2%) |
| Lethargy | 11 (9.2%) |
| Decreased appetite | 10 (8.4%) |
| Urinary Tract Infection | 10 (8.4%) |
| Elevated Alkaline phosphatase and/or Alanine Aminotransferase | 7 (6.0%) |
| Hypoglycemia | 4 (3.3%) |
| Hypercalcemia | 3 (2.5%) |
| Increased BUN | 2 (1.7%) |
| Bradycardia (<60 bpm) | 2 (1.7%) |
| Seizures/twitching | 2 (1.7%) |

[a]There were an additional 21 dogs enrolled with hypertension who remained hypertensive throughout the study.

During the first week of administration of PROIN ER, 15% of dogs had reported emesis, diarrhea, or decreased appetite which improved or resolved prior to the Day 21 visit.

Four deaths occurred during the study. One dog was euthanized for pulmonary metastasis and one dog for poor quality of life due to hindlimb weakness. One dog had emesis and died at home; upon necropsy a foreign body was present in the small intestine. The fourth dog had been treated for a urinary tract infection three weeks prior to sudden death of undetermined cause.

PROIN Chewable Tablets (NADA 141-324):

Table 3 below includes the most common adverse reactions observed in the masked, placebo-controlled 28-day clinical study involving 123 PROIN Chewable Tablet-treated dogs and 61 placebo-treated dogs. In addition, one dog exhibited disorientation, nervousness, a 7.7% loss of body weight, and hypertension with proteinuria. A second dog exhibited restless behavior, lethargy, a 2.8% body weight loss, and proteinuria.

**Table 3. Number and percentage of dogs with adverse reactions in the 28-day placebo-controlled clinical study for PROIN Chewable Tablets**

| Adverse Reactions | PROIN-treated (N=123) | Placebo-treated (N=61) |
|---|---|---|
| Emesis | 20.3% | 8.2% |
| Hypertension (≥160 mmHg)[a] | 19.5% | 14.7% |
| Anorexia | 16.3% | 3.3% |
| Body weight loss (>5%)[b] | 16.1% | 6.8% |
| Proteinuria | 13.0% | 8.2% |
| Anxiety/aggression/behavior change | 9.7% | 3.2% |
| Diarrhea | 7.3% | 9.8% |
| Polydipsia | 6.5% | 9.8% |
| Lethargy | 5.7% | 1.6% |
| Musculoskeletal Disorder | 3.2% | 1.6% |
| Insomnia/sleep disorder | 2.5% | 0.0% |

[a]One or more systolic blood pressure readings of ≥160 mmHg.

[b]The "N" for weight loss is PROIN-treated N=118 and placebo N=59 because seven dogs did not have a final weight at the time of withdrawal from the study.

One-hundred fifty-seven dogs continued into the 6-month open-label clinical study for PROIN Chewable Tablets. The most common adverse reactions are listed in Table 4 below. In addition, one dog exhibited progressively worsening hypertension with proteinuria. Five dogs enrolled in the study with pre-existing heart disease. Of these, one dog developed systolic failure with an unknown relation to treatment.

**Table 4. Number and percentage of dogs with adverse reactions in the 6-month open-label clinical study for PROIN Chewable Tablets**

| Adverse Reactions | Total N=125 |
|---|---|
| Hypertension (≥160 mmHg)[a] | 34.6% |
| Body weight loss (>5%) | 24.8% |
| Emesis | 19.7% |
| Proteinuria | 15.3% |
| Anorexia | 10.2% |
| Diarrhea | 6.4% |
| Lethargy | 5.7% |
| Anxiety/aggression/behavior change | 5.7% |

[a] Percent of dogs with systolic blood pressures of ≥160 mmHg on day -7 were 30.2% and on day 0 were 33.3%.

*Post Approval Experience for PROIN Chewable Tablets (2015):*

The following adverse reactions are based on voluntary, post approval reporting for PROIN Chewable Tablets (2015). Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The signs reported are listed in decreasing order of reporting frequency by body system:

Gastrointestinal: Emesis, anorexia, diarrhea, hypersalivation
Behavioral: Agitation, lethargy, vocalization, confusion
General body system: Polydipsia, weight loss, weakness, fever
Respiratory: Panting
Dermatological: Erythema, piloerection
Hepatic: Elevated serum alanine aminotransferase (ALT), elevated serum alkaline phosphatase (ALP)
Neurologic: Ataxia, seizures, tremors
Renal/Urinary: Renal failure, hematuria, urinary retention
Cardiovascular: Tachycardia, hypertension, bradycardia, arrhythmias
Sensory: Ophthalmic disorders, mydriasis and eye redness

In some cases, death, including euthanasia, has been reported. Sudden death was sometimes preceded by neurologic signs, vocalization, or collapse. A necropsy of one dog revealed subarachnoidal and intraventricular hemorrhage in the brain.

The following signs have been reported more often with a dose higher than the recommended dosage: agitation, arrhythmia, bradycardia, erythema, fever, hypersalivation, hypertension, lethargy, mydriasis, panting, piloerection, tachycardia, tremor, and urinary retention.

**Contact Information** For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, contact Pegasus Laboratories at 1-800-874-9764. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

**INFORMATION FOR DOG OWNERS:**
Always follow the dosage instructions for PROIN ER provided by your veterinarian. Give PROIN ER with food and do not split or crush the tablet. Monitor your dog after giving PROIN ER to be sure all of it was consumed. If you have difficulty giving PROIN ER, contact your veterinarian.

PROIN ER may cause increased thirst; therefore, provide dogs with ample fresh water.

If you forget to give your dog a dose, then resume dosing at the next scheduled dose. Keep PROIN ER in a secured location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

Contact your veterinarian immediately if the dog ingests more tablets than prescribed or if other pets ingest PROIN ER. In the case of accidental ingestion by humans, contact a physician immediately.

Contact your veterinarian if you notice restlessness, irritability, loss of appetite, the incontinence persists or worsens, or any other unusual signs.

Consult your veterinarian before administering PROIN ER with any other medications.

**CLINICAL PHARMACOLOGY:**
Phenylpropanolamine is a chemical analogue of the endogenous sympathomimetic amines. It is an alpha-adrenergic agent which has been reported to increase urethral tone in dogs.[2] Its mechanism of action is not well determined, but it is believed to cause the release of norepinephrine by indirectly stimulating both the alpha and beta-adrenergic receptors of the smooth muscle to increase smooth muscle tone of the urethra, bladder neck, and the internal urethral sphincter.[3,4]

In a crossover pharmacokinetic study of PROIN ER in fed and fasted dogs, post-prandial drug administration was associated with approximately a 23% increase in the maximum plasma concentration ($C_{max}$), but the area under the concentration vs time curve to the last quantifiable concentration ($AUC_{last}$) was similar in both fed and fasted states. The small decrease in the post-prandial $AUC_{last}$ appeared to be attributable to the corresponding increase in the terminal elimination rate constant under the fed conditions. The time to Cmax ($T_{max}$) was more variable in the fasted state, ranging from 1.5 to 8 hours compared to 2 to 6 hours for the fed state. The elimination half-life (t ½) was also more variable in the fasted state, ranging from 3.89 to 10.35 hours compared to 2.98 to 7.81 hours for the fed state.

**EFFECTIVENESS:**
Effectiveness of PROIN ER was demonstrated in a multi-center, prospective, open-label, 6-month study in client-owned dogs of various breeds. In this study, 119 dogs (113 spayed females and 6 neutered males, aged 1-16 years and weighing 4.9-81.8 kg) who were considered well controlled for signs of urinary incontinence (UI) while receiving PROIN Chewable Tablets for at least 30 days prior to study start were enrolled in the study. Of these dogs, 104 were evaluated for effectiveness. The owners continued to administer PROIN Chewable Tablets twice a day and recorded episodes of UI during a baseline period (Day -7 through Day -1). After the baseline period, the owners transitioned to administration of PROIN ER once a day, at the labeled dose (see **Dosage and Administration**), and recorded urinary accidents for 28 days.

The primary variable was the ratio of average daily incidence of UI during the 7 days preceding the Day 28 clinic visit compared to the baseline period. It was concluded that PROIN ER was effective for the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

**Table 5: Clinical Effectiveness Results for PROIN ER**

| Ratio | Number of Dogs N=104 |
|---|---|
| Ratio >1, indicating response measurement period was better than baseline period | 19 (18.3%) |
| Ratio of 1, indicating no difference between response measurement period and baseline period | 75 (72.1%) |
| Ratio <1, indicating response measurement period was worse than baseline period | 10 (9.6%) |

The secondary outcome variable was owner assessment of the control of UI at the end of the 28 day study period. The owner assessment was "improved" for 13 (12.5%) dogs, "stayed the same" for 90 (86.5%) dogs and "worsened" for 1 dog (1%).

**ANIMAL SAFETY:**
The safety of PROIN ER was established based on the safety data from PROIN Chewable Tablets (see below) and a comparative analysis of pharmacokinetic (PK) data for PROIN ER and PROIN Chewable Tablets. The statistical analysis of observed and simulated post-prandial pharmacokinetic data resulted in confidence limits consistent with equal or lower oral bioavailability for PROIN ER when administered once daily versus PROIN Chewable Tablets when administered twice daily. Therefore, the safety data from PROIN Chewable Tablets could be applied to PROIN ER. Emesis and hyperemia of the ventral abdomen were observed during the PK studies.

Target Animal Safety Study (PROIN Chewable Tablets, NADA 141-324)

In a target animal safety study, PROIN Chewable Tablets were administered to 32 healthy male and female Beagle dogs at 0, 2, 6 and 10 mg/kg of body weight (0, 1, 3 and 5 times the recommended dose; 8 dogs per group) twice daily for 26 consecutive weeks. The most pronounced finding was a dose-dependent increase in blood pressure. Mean systolic blood pressure was increased in all PPA-treated groups compared to the control, but mean values for all 4 groups were within the normal range. Mean diastolic and mean MAP (mean arterial pressure) were higher in the 3X and 5X groups, and in the 1X males. Dogs in the 3X and 5X groups had more individual systolic, diastolic, and MAP values above the normal range than the control group dogs. A dose-dependent decrease in heart rate was observed in the 3X and 5X dogs. In the 0, 1, 3, and 5X groups, 5%, 34%, 44%, and 40% of the total number of heart rates obtained from electrocardiograms for each group over the course of the study were below the normal range (70-120 beats per minute), with the lowest value being 51 bpm in 4 of the 1X group dogs. One dog in each of the 1X and 5X groups had an elevated heart rate between 150-180 beats per minute on at least 2 of the 13 physical exams. One dog in each of the 1X and 3X groups developed gallop heart sounds after treatment began that were noted in 12 of 13 and 6 of 13 physical exams respectively. Dogs in the PPA-treated groups exhibited anxious/restless behavior more frequently than the control group. One dog each in the 1X and 3X groups were responsible for the majority of the observations. A decline in mean body weight and body condition was observed in females in all 4 groups, including the control. One female in the 1X group lost 33% body weight. Emesis and loose stool occurred in a dose-related fashion, and most of the emesis episodes took place within 1 hour of dosing. Mean platelet counts were higher in at least one of the PPA-treated groups, with individual values up to 1.4X the upper limit of normal (ULN) in the 3X and 5X groups. The 3X and 5X groups had higher mean serum ALT values compared to the control. Mean ALT was within the normal range for all 4 groups. There were more dogs with ALT levels above the normal range in the 3 PPA-treated groups compared to the control, but increased values were transient and less than 1.8X ULN. All dogs had ALT values in the normal range at the conclusion of the study.

Tolerance study (PROIN Chewable Tablets, NADA 141-324)

In the separate tolerance study, 6 healthy female Beagle dogs were administered PROIN Chewable Tablets at 20 mg/kg body weight (10 times the recommended dose) twice daily for 21 consecutive days. Mean systolic blood pressure was increased in the 10X group compared to the control, but mean values were within the normal range for both groups. Mean diastolic pressures were above the normal range on days 7 and 21 for the 10X group, and day 14 for the control. The 10X dogs had hypertensive mean MAP values on days 7 and 21, whereas the control dog mean MAP values were in the normal range. There was a trend in 10X dogs for lower heart rates following initiation of PPA treatment. Four of 6 dogs in the 10X group had heart rates below the normal range on day 7, whereas none of the control dogs did. The 10X group dogs had increased hematocrit, hemoglobin, RBC counts, urine specific gravity, and water intake consistent with transient, sub-clinical dehydration that occurred shortly after PPA treatment was started. All 6 dogs in the 10X group developed emesis during the treatment period, whereas only 1 of the control dogs did. Most of the emesis episodes took place within 1 hour of dosing. Mean platelet counts were also higher in 10X dogs on all 3 exam days; mean values were above the normal range on day 7, with individual values up to 1.5X ULN. The 10X group had a higher mean serum ALT value on day 7 than the control. Mean ALT values for both groups were in the normal range on all 3 exam days, but 2 dogs in the 10X group had ALT values up to 1.4X ULN on day 7; these elevated values were transient, and all dogs had normal ALT values on days 14 and 21.

For either study, there was no evidence of chronic hypertension-induced target organ damage; there were no clinical findings attributable to PPA on the ophthalmic exams, electrocardiogram evaluation, or gross necropsy and histopathology.

**STORAGE:** Store at controlled room temperature 20-25°C (68-77°F), excursions permitted between 15-40°C (59-104°F).

**HOW SUPPLIED:** PROIN ER tablets contain 18, 38, 74 or 145 mg phenylpropanolamine hydrochloride per tablet. PROIN ER is packaged in bottles containing 30 or 90 tablets.

**REFERENCES:**


[1] Watson R, et al. Ephedra alkaloids inhibit platelet aggregation. Blood coagulation and Fibrinolysis, 2010, 21:266-271.

[2] Richter K.P., Ling G.V. Clinical response and urethral pressure profile changes after phenylpropanolamine in dogs with primary sphincter incompetence. JAVMA, Vol. 187, No 6, September 15, 1985. 605-611.

[3] Scott, L., Leddy M. and Bernay, F. Evaluation of phenylpropanolamine in the treatment of urethral sphincter mechanism incompetence in the bitch. J. Small Anim. Pract. 2002;43(11): 493-6.

[4] Noel, S., et al. Combined pharmacokinetic and urodynamic study of the effects of oral administration of phenylpropanolamine in female Beagle dogs. Vet. Journal, 2010; 184(2): 201-207.





01/2019

**Manufactured By:**
**Pegasus Laboratories, Inc.**
**Employee-Owned**
**Pensacola, Florida 32514, USA**
**Manufactured in the USA**



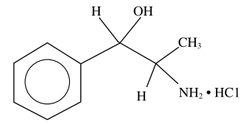

# PROIN® (phenylpropanolamine hydrochloride)

## Chewable Tablets

**For oral use in dogs only**

**Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**Description:** PROIN (phenylpropanolamine hydrochloride) is a sympathomimetic amine closely related to ephedrine. Phenylpropanolamine hydrochloride (PPA) is the nonproprietary designation for benzenemethanol, α-(1-aminoethyl)-, hydrochloride, (R*, S*)-, (±). The empirical formula is $C_9H_{13}NO{\cdot}HCl$ and the molecular weight is 187.67. It is a white crystalline compound having a slight aromatic odor. PPA is freely soluble in water and alcohol but is practically insoluble in ether, benzene and chloroform. The chemical structure of phenylpropanolamine hydrochloride is:




**Indication:** PROIN is indicated for the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

Dosage and Administration: The total recommended dosage for oral administration is 2 mg/kg (0.91 mg/lb) of body weight twice daily. PROIN is scored and dosage should be calculated in half-tablet increments.

**Warnings:** Not for human use. Keep out of reach of children. Consult a physician in case of accidental ingestion by humans.

**Precautions:** PROIN may cause increased thirst; therefore, provide ample fresh water.

Overdose has been associated with dogs chewing through closed bottles of PROIN and consuming multiple tablets. Therefore, it is important to store PROIN Chewable Tablets out of reach of dogs and other pets in a secured location.

Use in dogs with incontinence due to a urinary tract infection will mask symptoms. PROIN is not effective in dogs with incontinence due to neurologic disease or malformations.

PROIN may cause hypertension; therefore, use with caution in dogs with pre-existing heart disease, hypertension, liver disease, kidney insufficiency, diabetes, glaucoma, and conditions with a predilection for hypertension. Use with caution in dogs receiving sympathomimetic drugs, tricyclic antidepressants, or monoamine oxidase inhibitors as increased toxicity may result. Use with caution in dogs administered halogenated gaseous anesthetics as this may increase the risk of cardiac arrhythmias.

A laboratory study on human blood revealed that PPA used in conjunction with aspirin may potentiate decreased platelet aggregation.1

The safe use of PROIN in dogs used for breeding purposes, during pregnancy or in lactating bitches, has not been evaluated.

**Adverse Reactions "Pre Approval Experience":** A placebo-controlled clinical study involving 123 PROIN-treated dogs and 61 placebo-treated dogs was conducted for 28 days. The most common adverse reactions are shown in Table 1 below. In addition, one dog exhibited disorientation, nervousness, a 7.7% loss of body weight, and hypertension with proteinuria. A second dog exhibited restless behavior, lethargy, a 2.8% body weight loss, and proteinuria.¬

**Table 1: Number and percentage of dogs with adverse reactions in the 28-day placebo-controlled clinical study**

| Adverse reactions | PROIN-treated (N=123) | Placebo-treated (N=61) |
|---|---|---|
| Emesis | 20.3% | 8.2% |
| Hypertension (≥ 160 mmHg)[1] | 19.5% | 14.7% |
| Anorexia | 16.3% | 3.3% |
| Body weight loss (>5%)[2] | 16.1% | 6.8% |
| Proteinuria | 13.0% | 8.2% |
| Anxiety/aggression/behavior change | 9.7% | 3.2% |
| Diarrhea | 7.3% | 9.8% |
| Polydipsia | 6.5% | 9.8% |
| Lethargy | 5.7% | 1.6% |
| Musculoskeletal Disorder | 3.2% | 1.6% |
| Insomnia/sleep disorder | 2.5% | 0.0% |

[1]One or more systolic blood pressure readings of ≥ 160 mmHg

[2]The "N" for weight loss is PROIN-treated N=118 and placebo N=59 because seven dogs did not have a final weight at the time of withdrawal from the study.

One-hundred fifty seven dogs continued into the 6-month open-label clinical study. The most common adverse reactions are listed in Table 2 below. In addition, one dog exhibited progressively worsening hypertension with proteinuria. Five dogs enrolled in the study with pre-existing heart disease. Of these, one dog developed systolic failure with an unknown relation to treatment.

**Table 2: Number and percentage of dogs with adverse reactions in the 6-month open-label clinical study**

| Adverse reactions | Total N=125 |
|---|---|
| Hypertension (≥ 160 mmHg)[1] | 34.6% |
| Body Weight loss (≥ 5%) | 24.8% |
| Emesis | 19.7% |
| Proteinuria | 15.3% |
| Anorexia | 10.2% |
| Diarrhea | 6.4% |
| Lethargy | 5.7% |
| Anxiety/behavior change/aggression | 5.7% |

[1]Percent of dogs with systolic blood pressures of ≥160 mmHg on day -7 were 30.2% and on day 0 were 33.3%.

**POST APPROVAL EXPERIENCE (2015):**
The following adverse events are based on voluntary, post approval reporting. Not all adverse events are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The signs reported are listed in decreasing order of reporting frequency by body system:
Gastrointestinal: Vomiting, anorexia, diarrhea, hypersalivation,
Behavioral: Agitation, lethargy, vocalization, confusion,
General body system: Polydipsia, weight loss, weakness, fever,
Respiratory: Panting,
Dermatological: Erythema, piloerection,
Hepatic: Elevated serum alanine aminotransferase (ALT), elevated serum alkaline phosphatase (ALP),
Neurologic: Ataxia, seizures, tremors,
Renal/Urinary: Renal failure, hematuria, urinary retention,
Cardiovascular: Tachycardia, hypertension, bradycardia, arrhythmias,
Sensory: Ophthalmic disorders, mydriasis and eye redness.

In some cases, death, including euthanasia, has been reported. Sudden death was sometimes preceded by neurologic signs, vocalization, or collapse. A necropsy of one dog revealed subarachnoidal and intraventricular hemorrhage in the brain.

The following signs have been reported more often with a dose higher than the recommended dosage: agitation, arrhythmia, bradycardia, erythema, fever, hypersalivation, hypertension, lethargy, mydriasis, panting, piloerection, tachycardia, tremor, and urinary retention.

For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, contact Pegasus Laboratories at 1-800-874-9764. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

**Information for Owner or Person Treating Animal:** Always follow the dosage instructions for PROIN provided by your veterinarian. Monitor your dog after giving PROIN to be sure all of it was consumed. If you have difficulty giving PROIN, contact your veterinarian.

It may take several days of treatment with PROIN before urinary incontinence improves. If you miss a dose, give it as soon as you remember. If it is close to the time for the next dose, skip the dose you missed and go back to the regular dosing schedule. Do not give two doses at once. PROIN should only be given to the dog for which it was prescribed. Because PROIN is flavored, store in a secure area.

Dogs may willingly consume more than the recommended dosage of PROIN Chewable Tablets. Instances of dogs chewing through closed bottles of PROIN and eating the bottles contents have been reported. Keep the product in a secured storage area out of the reach of pets in order to prevent accidental ingestion or overdose. Contact your veterinarian immediately if the dog ingests more tablets than prescribed or if other pets ingest PROIN Chewable Tablets. In the case of accidental ingestion by humans, contact a physician immediately.

Contact your veterinarian if you notice restlessness or irritability, loss of appetite, the incontinence persists or worsens, or any other unusual signs.

Consult your veterinarian before using PROIN with any other medications.

**Clinical Pharmacology:** Phenylpropanolamine is a chemical analogue of the endogenous sympathomimetic amines. It is an a-adrenergic agent which has been reported to increase urethral tone in dogs.[2] Its mechanism of action is not well determined, but it is believed to cause the release of norepinephrine by indirectly stimulating both the alpha and beta-adrenergic receptors of the smooth muscle to increase smooth muscle tone of the urethra, bladder neck, and the internal urethral sphincter.[3,4]

The pharmacokinetics of phenylpropanolamine in dogs has not been well studied. In humans, phenylpropanolamine is readily absorbed after oral administration of solid dosage forms and has an onset of action of approximately 15-30 minutes and duration of effect of about three hours. In a published study in dogs, phenylpropanolamine disposition was characterized in three dogs administered phenylpropanolamine intravenously and orally in immediate-release and controlled-release formulations.5 The terminal elimination half-life averaged 3.5 ± 0.5 hours after the intravenous dose. Oral absorption from the immediate-release capsule was rapid and bioavailability was 98.2 ± 6.9 percent. Absorption of phenylpropanolamine from the controlled-release dosage form was biphasic; an initial rapid phase was followed by a second, slower absorption phase which continued over 16 hours. Plasma concentrations then declined with a half-life roughly parallel to the intravenous and oral immediate-release half-lives. Oral bioavailability from the controlled-release tablet was 93.7 ± 5.9 percent.

**Effectiveness:** A 28-day placebo-controlled clinical study was conducted in 21 study sites across the U.S. The study included 184 dogs with urinary incontinence due to sphincter hypotonus of which 127 dogs (100 female, 27 male) were evaluated for effectiveness. Dogs were randomly assigned either to receive 2 mg/kg PROIN (123 dogs) or placebo (61 dogs) administered orally twice daily for 28 days. PROIN was effective in controlling urinary incontinence based on a decrease in urinary accidents per week. Changes to hematology and serum chemistry were not considered clinically significant or related to treatment.

**Table 3: Mean urinary accidents per week by treatment group, females**

| Week | Mean Urinary Accidents (PROIN-treated, N=66) | Mean Urinary Accidents (Placebo, N=34) |
|---|---|---|
| Pretreatment | 9.0 | 7.8 |
| 1 | 3.9 | 4.8 |
| 2 | 2.5 | 4.1 |
| 3 | 1.5 | 3.1 |
| 4 | 1.6 | 2.8 |

One-hundred fifty seven dogs continued into the 6-month open-label clinical study conducted in 21 study sites across the U.S. All the dogs had participated in the 28-day placebo-controlled linical study and had urinary incontinence due to sphincter hypotonus. Dogs were administered 2 mg/kg PROIN orally twice daily for 180 days. PROIN was effective for the control of urinary incontinence for 180 days based on 98.1% owner satisfaction. The dogs averaged just over one accident per dog per week. Changes in hematology and serum chemistry were not considered clinically significant or related to treatment.

The dogs voluntarily consumed 53.9% of the doses and 33.7% of the doses in food. The owners pilled the dogs 12.1% of the doses and were unable to administer 0.3% of the doses.

**Animal Safety Studies:** In a target animal safety study, PROIN was administered to 32 healthy male and female Beagle dogs at 0, 2, 6 and 10 mg/kg of body weight (0, 1, 3 and 5 times the recommended dose; 8 dogs per group) twice daily for 26 consecutive weeks. The most pronounced finding was a dose-dependent increase in blood pressure. Mean systolic blood pressure was increased in all PPA-treated groups compared to the control, but mean values for all 4 groups were within the normal range. Mean diastolic and mean MAP (mean arterial pressure) were higher in the 3X and 5X groups, and in the 1X males. Dogs in the 3X and 5X groups had more individual systolic, diastolic, and MAP values above the normal range than the control group dogs. A dose-dependent decrease in heart rate was observed in the 3X and 5X dogs. In the 0, 1, 3, and 5X groups, 5%, 34%, 44%, and 40% of the total number of heart rates obtained from electrocardiograms for each group over the course of the study were below the normal range (70-120 beats per minute), with the lowest value being 51 bpm in 4 of the 1X group dogs. One dog in each of the 1X and 5X groups had an elevated heart rate between 150-180 beats per minute on at least 2 of the 13 physical exams. One dog in each of the 1X and 3X groups developed gallop heart sounds after treatment began that were noted in 12 of 13 and 6 of 13 physical exams respectively. Dogs in the PPA-treated groups exhibited anxious/restless behavior more frequently than the control group. One dog each in the 1X and 3X groups were responsible for the majority of the observations. A decline in mean body weight and body condition was observed in females in all 4 groups, including the control. One female in the 1X group lost 33% body weight. Vomiting and loose stool occurred in a dose-related fashion, and most of the vomiting episodes took place within 1 hour of dosing. Mean platelet counts were higher in at least one of the PPA-treated groups, with individual values up to 1.4X the upper limit of normal (ULN) in the 3X and 5X groups. The 3X and 5X groups had higher mean serum ALT values compared to the control. Mean ALT was within the normal range for all 4 groups. There were more dogs with ALT levels above the normal range in the 3 PPA-treated groups compared to the control, but increased values were transient and less than 1.8X ULN. All dogs had ALT values in the normal range at the conclusion of the study.

In a separate tolerance study, 6 healthy female Beagle dogs were administered PROIN at 20 mg/kg body weight (10 times the recommended dose) twice daily for 21 consecutive days. Mean systolic blood pressure was increased in the 10X group compared to the control, but mean values were within the normal range for both groups. Mean diastolic pressures were above the normal range on days 7 and 21 for the 10X group, and day 14 for the control. The 10X dogs had hypertensive mean MAP values on days 7 and 21, whereas the control dog mean MAP values were in the normal range. There was a trend in 10X dogs for lower heart rates following initiation of PPA treatment. Four of 6 dogs in the 10X group had heart rates below the normal range on day 7, whereas none of the control dogs did. The 10X group dogs had increased hematocrit, hemoglobin, RBC counts, urine specific gravity, and water intake consistent with transient, sub-clinical dehydration that occurred shortly after PPA treatment was started. All 6 dogs in the 10X group vomited at least once during the treatment period, whereas only 1 of the control dogs did. Most of the vomiting episodes took place within 1 hour of dosing. Mean platelet counts were also higher in 10X dogs on all 3 exam days; mean values were above the normal range on day 7, with individual values up to 1.5X ULN. The 10X group had a higher mean serum ALT value on day 7 than the control. Mean ALT values for both groups were in the normal range on all 3 exam days, but 2 dogs in the 10X group had ALT values up to 1.4X ULN on day 7; these elevated values were transient, and all dogs had normal ALT values on days 14 and 21.

For either study, there was no evidence of chronic hypertension-induced target organ damage; there were no clinical findings attributable to PPA on the ophthalmic exams, electrocardiogram evaluation, or gross necropsy and histopathology.

**Storage:** Store at controlled room temperature 20-25°C (68-77°F), excursions permitted between 15-40°C (59-104°F)

**How Supplied:** PROIN is scored and contains 25, 50 or 75 mg phenylpropanolamine hydrochloride per tablet. PROIN is packaged in bottles containing 60 or 180 tablets.

NADA #141-324, Approved by FDA.

PROIN® is a registered trademark of Pegasus Laboratories, Inc.

**References:**


[1]Watson R, et al. Ephedra alkaloids inhibit platelet aggregation. Blood Coagulation and Fibrinolysis, 2010, 21: 266-271.

[2]Richter K.P., Ling G.V. Clinical response and urethral pressure profile changes after phenylpropanolamine in dogs with primary sphincter incompetence. JAVMA, Vol. 187, No 6, September 15, 1985. 605-611.

[3]Scott, L., Leddy M. and Bernay, F. Evaluation of phenylpropanolamine in the treatment of urethral sphincter mechanism incompetence in the bitch. J. Small Anim. Pract. 2002; 43(11): 493-6.

[4]Noel, S., et al. Combined pharmacokinetic and urodynamic study of the effects of oral administration of phenylpropanolamine in female Beagle dogs. Vet. Journal, 2010; 184(2): 201-207.

[5]Hussain, M.A., Aungst, B.J., Lam, G. and Shefter, E. Phenylpropanolamine pharmacokinetics in dogs after intravenous, oral, and oral controlled-release doses. Biopharm Drug Dispos, Vol. 8, No. 5, September-October 1987. 497-505.



*Manufactured by:*
**Pegasus Laboratories, Inc.**
*An Employee-Owned Company*
Pensacola, FL 32514, USA

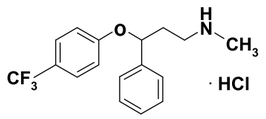
11-2014

PRESCRIBING INFORMATION FOR VETERINARIAN 10-2017

# Reconcile® (fluoxetine hydrochloride)
## Chewable Tablets

**Caution:**
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**Description:**
RECONCILE is a chewable, flavored tablet that contains fluoxetine hydrochloride. RECONCILE chewable tablets are available in 8, 16, 32, and 64 mg tablet strengths for oral administration to dogs. The active ingredient in RECONCILE chewable tablets is fluoxetine hydrochloride, a selective serotonin reuptake inhibitor (SSRI). The molecular weight of fluoxetine is 345.79. The structural formula is depicted below.




fluoxetine hydrochloride
$C_{17}H_{18}F_3NO \cdot HCl$

**Indications:**
RECONCILE chewable tablets are indicated for the treatment of canine separation anxiety in conjunction with a behavior modification plan.

**Dosage and Administration:**
The recommended dose of RECONCILE chewable tablets is 1–2 mg/kg (0.5–0.9 mg/lb) administered once daily, in conjunction with a behavior modification plan. A typical behavior modification plan consists of the pet owner implementing standard training techniques based on principles such as rewarding appropriate behavior; coming and going in a manner that does not elicit inappropriate responses from the dog; and teaching the dog to be content while alone.

**Table 1: Recommended Dose of RECONCILE Chewable Tablets**

| Dog Weight (lb) | Dog Weight (kg) | No. of Tablets/Day | Tablet Strength (mg) |
|---|---|---|---|
| 8.8 – 17.6 | 4.0 – 8.0 | 1 | 8 |
| 17.7 – 35.2 | 8.1 – 16.0 | 1 | 16 |
| 35.3 – 70.4 | 16.1 – 32.0 | 1 | 32 |
| 70.5 – 140.8 | 32.1 – 64.0 | 1 | 64 |

The effectiveness and safety of RECONCILE chewable tablets was demonstrated in a field study in client-owned dogs (see **EFFECTIVENESS** and **ADVERSE REACTIONS**). At the end of the 8-week study, 73% of dogs treated with RECONCILE chewable tablets showed significant improvement (p=0.010), as compared to behavior modification alone (51%). During the course of therapy, 42% of dogs showed improvement within the first week, which was significantly greater (p=0.005) than with behavior modification alone (18%). The patient's response to therapy should be monitored. If no improvement is noted within 8 weeks, case management should be reevaluated.

The effectiveness and clinical safety of RECONCILE chewable tablets for long-term use (i.e., for more than 8 weeks) has not been evaluated. RECONCILE chewable tablets were evaluated at the recommended label dose for one year in a laboratory safety study in dogs (see **ANIMAL SAFETY**).

Professional judgment should be used in monitoring the patient's response to therapy to determine the need to continue treatment with RECONCILE chewable tablets beyond 8 weeks. To discontinue therapy, it is not necessary to taper or reduce doses because of the long half-life of this product. Continued behavioral modification is recommended to prevent recurrence of the clinical signs.

RECONCILE chewable tablets are readily consumed by dogs or can be administered like other tablet medications, and can be given with or without food.

Professional discretion should be used in determining the need for dose reduction in the event of a possible adverse reaction. Approximately half of patients tolerate a return to the previous dose after 1–2 weeks on a reduced schedule (see **ADVERSE REACTIONS**).

If a dose is missed, the next scheduled dose should be administered as prescribed. Do not increase or double the dose.

**Contraindications:**
RECONCILE chewable tablets are contraindicated for use in dogs with epilepsy or a history of seizures. RECONCILE chewable tablets should not be given concomitantly with drugs that lower the seizure threshold (e.g., phenothiazines such as acepromazine or chlorpromazine).

RECONCILE chewable tablets should not be given in combination with a monoamine oxidase inhibitor (MAOI) [e.g., selegiline hydrochloride (L-deprenyl) or amitraz], or within a minimum of 14 days of discontinuing therapy with an MAOI.

RECONCILE chewable tablets are contraindicated in dogs with a known hypersensitivity to fluoxetine HCl or other SSRIs.

Because fluoxetine and its major metabolite, norfluoxetine, have long half-lives, a 6-week washout interval should be observed following discontinuation of therapy with RECONCILE chewable tablets prior to the administration of any drug that may adversely interact with fluoxetine or norfluoxetine.

**Warnings:**
Not for use in humans. **Keep out of reach of children.** In case of accidental ingestion seek medical attention immediately. In humans, the most common symptoms associated with over dosage include seizures, somnolence, nausea, tachycardia, and vomiting. In case of ingestion by a human, contact a physician immediately. For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call 1-800-874-9764.

**Precautions:**
RECONCILE chewable tablets are not recommended for the treatment of aggression. RECONCILE chewable tablets have not been clinically tested for the treatment of other behavioral disorders. Studies to determine the effects of RECONCILE chewable tablets in breeding, pregnant, or lactating dogs and in patients less than 6 months of age have not been conducted.

Seizures may occur in dogs treated with RECONCILE chewable tablets, even in dogs without a history of epilepsy or seizures (see **ADVERSE REACTIONS**).

Before prescribing RECONCILE chewable tablets, a comprehensive physical examination should be conducted to rule out causes of inappropriate behavior unrelated to separation anxiety. The examination should include a thorough history and assessment of the patient's household environment and standard practice laboratory tests as appropriate for the patient's age and health status. Veterinarians should be familiar with the risks and benefits of the treatment of behavioral disorders in dogs before initiating therapy. Inappropriate use of RECONCILE chewable tablets, i.e., in the absence of a diagnosis or without concurrent behavior modification, may expose the animal to unnecessary adverse reactions and may not provide any lasting benefit of therapy.

RECONCILE chewable tablets have not been evaluated with drugs that affect the cytochrome P450 enzyme system. RECONCILE chewable tablets should be used with caution when co-administered with any drug that affects the cytochrome P450 enzyme system (for example, ketaconazole). Studies to assess the interaction of RECONCILE chewable tablets with tricyclic antidepressants (TCAs) (for example, amitriptyline and clomipramine) have not been conducted. The minimum washout period to transition dogs from TCAs to RECONCILE chewable tablets has not been evaluated. Published pharmacokinetic data demonstrates that TCAs are cleared 4 days following discontinuation.[1, 2]

**Adverse Reactions:**
In two North American multi-site field studies, which included a total of 427 dogs, the following adverse reactions were observed:

*Seizures:*
In one study, one of 112 dogs in the control group and three of 117 dogs that received RECONCILE chewable tablets experienced the serious adverse reaction of seizures. One of the three dogs treated with RECONCILE chewable tablets experienced two seizures 10 days after the end of therapy. Despite escalating phenobarbital doses, the seizures continued and this dog died in status epilepticus approximately six months after the first seizure. Another of the three dogs treated with RECONCILE chewable tablets had experienced one seizure approximately 1½ years prior to study enrollment immediately after receiving head trauma. No additional seizures were reported to have occurred until 45 days after concluding treatment with RECONCILE chewable tablets. During the 1½-year period since the second seizure, this dog's seizure activity increased from single seizures to cluster seizures despite increasing doses of phenobarbital and the addition of oral potassium bromide and rectal diazepam. The third dog treated with RECONCILE chewable tablets and the control dog experienced one seizure 24 days and 35 days, respectively, after the start of therapy; no anticonvulsant therapy was initiated and no further seizures were reported in either dog.

In the second study, one of 99 dogs treated with RECONCILE chewable tablets and one of 99 dogs treated with the control tablet experienced the serious adverse reaction of seizures 9 and 27 days, respectively, after initiation of therapy. The dog treated with RECONCILE chewable tablets was subsequently diagnosed with vestibular disease and the control dog had a history of recurrent hind leg weakness.

In a European multi-site study, 234 dogs were treated with daily doses of fluoxetine chewable tablets ranging from 0.25 mg/kg to 4 mg/kg. One dog treated with a daily dose of 0.4 mg/kg for one month experienced one seizure one week after discontinuing therapy. No anticonvulsant therapy was initiated and no further seizures were reported.

*Weight loss:*
Of the dogs in the two North American field studies with body weight measurements throughout the study (n=196 and n=185 in the RECONCILE chewable tablets and control group, respectively), a 5% or greater weight loss (when compared to initial, pre-study body weight) was observed in 58 (29.6%) of dogs treated with RECONCILE chewable tablets and 24 (13.0%) of dogs in the control group. No dogs were withdrawn from clinical studies due to weight loss alone. The following table shows the number of dogs with weight loss, stratified by percent weight loss relative to initial body weight.

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[1] *Plumb DC. Amitriptyline. Veterinary Drug Handbook 5th Edition (Pocket Edition). Iowa State Press. Ames, IA. Page 39, 2002.*

[2] *Hewson CJ, et.al. The pharmacokinetics of clomipramine and desmethylclomipramine in dogs: parameter estimates following a single oral dose and 28 consecutive daily doses of clomipramine. J Vet Pharmacol Therap 21:214-222, 1998.*



**Table 2: Dogs with Weight Loss (stratified by percent loss relative to initial body weight)**

| Treatment Group | ≥ 5% to < 10% Number (%) | ≥ 10 to < 15% Number (%) | ≥ 15% Number (%) |
|---|---|---|---|
| RECONCILE chewable tablets | 44 (22.5%) | 13 (6.6%) | 1[a] (0.5%) |
| Control | 20 (10.8%) | 4 (2.2%) | 0 (0%) |

[a] This dog lost 20% of its initial body weight and was the same dog that died in status epilepticus.

**Other adverse reactions:**
Additional adverse reactions observed in dogs treated with RECONCILE chewable tablets at a rate of 1% or greater were:

**Table 3: Adverse Reactions Reported in the North American Field Studies**

| | RECONCILE Chewable Tablets, n=216 | | Control,* n=211 | |
|---|---|---|---|---|
| **Adverse Reaction** | n | % | n | % |
| Calm/Lethargy/Depression | 71 | 32.9 | 22 | 10.4 |
| Decreased Appetite | 58 | 26.9 | 13 | 6.2 |
| Vomiting | 37 | 17.1 | 28 | 13.3 |
| Shaking/Shivering/Tremor | 24 | 11.1 | 4 | 1.9 |
| Diarrhea | 21 | 9.7 | 17 | 8.1 |
| Restlessness | 16 | 7.4 | 8 | 3.8 |
| Excessive Vocalization (Including Whining) | 13 | 6.0 | 7 | 3.3 |
| Aggression | 9 | 4.2 | 13 | 6.2 |
| Otitis Externa | 6 | 2.8 | 2 | 0.9 |
| Disorientation | 5 | 2.3 | 1 | 0.5 |
| Incoordination | 5 | 2.3 | 0 | 0.0 |
| Constipation | 3 | 1.4 | 0 | 0.0 |
| Excessive Salivation | 3 | 1.4 | 4 | 1.9 |

* The control group received the tablet formulation without fluoxetine.

*Dose Reduction:*
Twenty dogs in the RECONCILE chewable tablet group and five dogs in the control group required a reduction in dose due to unacceptable adverse reactions, generally anorexia, vomiting, shaking and depression. Lowering the dose eliminated or reduced the severity of these adverse reactions in the RECONCILE chewable tablet group only. Resumption of the full dose of RECONCILE chewable tablets resulted in a return of the initial adverse reactions in approximately half of the affected dogs. The majority of these adverse reactions were intermittent and mild. However, one dog experienced recurrence of severe adverse reactions, which necessitated withdrawal from the study for that dog. Additionally, two dogs required a second dose reduction of RECONCILE chewable tablets. Effectiveness was maintained in a majority of those dogs in which a dose reduction was necessary.

**Post Approval Experience (Rev. 2010):**
The following adverse events are based on post-approval adverse drug experience reporting with RECONCILE chewable tablets. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data.

The following adverse events are listed in decreasing order of reported frequency: decreased appetite, depression/lethargy, shaking/shivering/tremor, vomiting, restlessness and anxiety, seizures, aggression, diarrhea, mydriasis, vocalization, weight loss, panting, confusion, incoordination, and hypersalivation.

For a copy of the Safety Data Sheet (SDS) or to report suspected adverse drug events, contact Pegasus Laboratories at 1-800-874-9764. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/AnimalVeterinary/SafetyHealth.

**Clinical Pharmacology:**
Fluoxetine exerts its effect by inhibiting the reuptake of serotonin at the pre-synaptic neuron. Fluoxetine does not act as a sedative. Fluoxetine is well absorbed after oral administration (~72%). It is largely metabolized in the liver by cytochrome P-450 enzyme system to norfluoxetine, an equipotent SSRI that contributes to the efficacy of RECONCILE chewable tablets.

After a single dose, and also at steady state, calculations were made as follows:

**Table 4: Single Dose* Pharmacokinetic Parameters of Fluoxetine Hydrochloride (mean ± standard error).**

| | $AUC_{0-\infty}$ (µg•hr/mL) | $C_{max}$ (ng/mL) | $T_{max}$ (hr) | $T_{1/2}$ (hr) | $T_{1/2}$ Range (hr) |
|---|---|---|---|---|---|
| Fluoxetine | 1.388 (±0.137) | 126.6 (±12.3) | 1.8 (±0.2) | 6.2 (±0.8) | 3.0 – 12.9 |
| Norfluoxetine | 11.44 (±0.74) | 138.3 (±9.6) | 12.8 (±1.7) | 49 (±3) | 33.0 – 64.0 |

*approximately 2 mg/kg body weight

In a 21-day study, fluoxetine was administered daily at a dose of 0.75, 1.5 and 3.0 mg/kg to laboratory Beagles. The maximum plasma concentration ($C_{max}$) and area under the plasma concen-tration time curve (AUC) for fluoxetine were approximately dose proportional between 0.75 and 1.5 mg/kg, with a greater than dose proportional increase at 3 mg/kg. Norfluoxetine $C_{max}$ and AUC were generally dose proportional.

Although steady state appeared to be reached within 10 days in the 21-day study, a continuous increase in trough concentrations was observed in a one year, multiple-dose laboratory safety study. In this study, dogs administered a 1 mg/kg dose of fluoxetine had plasma fluoxetine concentrations that continued to increase over the one-year dosing period. A similar increase in concentrations was observed with norfluoxetine. This phenomenon was not observed at higher doses. During the one-year dosing interval and the subsequent two-month recovery period, there were no changes in the nature and frequency of adverse reactions observed as compared to those seen by Day 28 of fluoxetine administration.

**Effectiveness:**
In one randomized multi-centered, double-blinded, vehicle-controlled study of 8 weeks duration, 229 dogs were evaluated at 34 investigative sites in the United States and Canada. One hundred seventeen dogs were randomized to 1–2 mg/kg/day of RECONCILE chewable tablets and 112 dogs were randomized to the control group. Both groups underwent concurrent behavior modification. In seven of the eight weeks, the percentage of dogs with improved overall separation anxiety scores was significantly higher ($p < 0.05$) among dogs treated with RECONCILE chewable tablets compared to dogs that received the control tablet. At the end of the study, 73% of dogs treated with RECONCILE chewable tablets showed significant improvement (p=0.010) as compared to 51% of dogs treated with behavior modification alone.

Dogs treated with RECONCILE chewable tablets also showed improvement in destructive behavior, excessive vocalization, and restlessness over dogs that received the control tablet. In addition, dogs in both groups experienced improvement in inappropriate urination, inappropriate defecation, excessive salivation, excessive licking/grooming, shaking/shivering and depression. Overall separation anxiety severity scores improved more rapidly for dogs taking RECONCILE chewable tablets than those dogs receiving the control tablet. The same effect was also noted for the individual scores for excessive vocalization and depression.

**Animal Safety:**
In a one-year laboratory safety study, dogs were dosed daily at 1, 4.5, and 20 mg/kg/day of a gelatin capsule filled with fluoxetine powder. Based upon the results of a relative bioavailability study comparing the fluoxetine-filled capsule versus the RECONCILE chewable tablets, the corresponding equivalent doses were 0.87, 3.9, and 17.4 mg/kg/day of RECONCILE chewable tablets (where the average ratio of fluoxetine AUC values for RECONCILE chewable tablets/fluoxetine-filled capsule = 1.15).

Three of five female dogs in the 20 mg/kg group died or were euthanized during the first six months of the study. The high dose was decreased to 10 mg/kg/day (equivalent to 8.7 mg/kg/day of RECONCILE chewable tablets) for the last six months of the treatment, and all remaining dogs completed the study. One dog in the 1 mg/kg group (equivalent to 0.87 mg/kg/day of RECONCILE chewable tablets) and two dogs in the 20 mg/kg group (equivalent to 17.4 mg/kg/day of RECONCILE chewable tablets) experienced a seizure. Aggressive behavior, ataxia, salivation at dosing, hyperesthesia, nystagmus, thin body condition, weakness, lethargy, diarrhea and head tilt were also noted in the high dose group. Anorexia, tremors, decreased pupillary light response, mydriasis, vomiting, and decreased weight gain were observed in all treatment groups, but occurred more frequently in the high dose group. With the exception of decreased weight gain, all abnormal observations resolved by the end of a two-month recovery period. Evidence of phospholipidosis was noted in the lung, liver, adrenal glands, lymph nodes, spleen, retina and white blood cells of all groups, which resolved during the recovery period. Fluoxetine caused no marked or consistent effects on hematology, blood chemistries or urinalysis. Bradycardia was absent on the electrocardiogram in the control and lowest dose groups, but was mildly present in a dose-dependent manner in the two higher dose groups. There were no effects noted on gross organ examination.

**Storage Information:**
Store at 20–25°C (68–77°F). Excursions permitted between 15–30°C (59–86°F).
Do not remove desiccant from the bottle.
Completely close bottle between uses.

**How Supplied:**
RECONCILE is supplied in 8mg, 16mg, 32mg and 64mg strengths; as 30 tablets per bottle, with a child-resistant cap.

NADA #141-272, Approved by FDA

**Manufactured by:**
Pegasus Laboratories, Inc.
Employee-Owned
Pensacola, FL 32514
Manufactured in the USA

# ReBalance®

## Sulfadiazine/Pyrimethamine Oral Suspension

NADA 141-240, Approved by FDA

**ReBalance® Antiprotozoal Oral Suspension (Sulfadiazine and Pyrimethamine)**

**CAUTION:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**DESCRIPTION: ReBalance Antiprotozoal Oral Suspension** is supplied in 946.4 mL (1 quart) bottles. Each mL of **ReBalance Antiprotozoal Oral Suspension** contains 250 mg sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine.

**INDICATIONS: ReBalance Antiprotozoal Oral Suspension** is indicated for the treatment of horses with equine protozoal myeloencephalitis (EPM) caused by Sarcocystis neurona.

**DOSAGE AND ADMINISTRATION: ReBalance Antiprotozoal Oral Suspension** is to be administered at a dose of 20 mg/kg sulfadiazine and 1 mg/kg pyrimethamine daily or 4 mL of **ReBalance Antiprotozoal Oral Suspension** per 110 lb. (50 kg) of body weight once per day. The duration of treatment is dependent upon clinical response, but the usual treatment regimen ranges from 90 to 270 days. Administer orally by suitable dosing syringe at least one hour prior to feeding with hay or grain. Insert nozzle of syringe through the interdental space and deposit the dose on the back of the tongue by depressing the plunger. Shake well before each use.

**CONTRAINDICATIONS:** The use of **ReBalance Antiprotozoal Oral Suspension** is contraindicated in horses with known hypersensitivity to sulfonamide drugs or pyrimethamine.

**WARNINGS:** For use in horses only. Do not use in horses intended for human consumption. Not for human use. Keep out of the reach of children.

**PRECAUTIONS:** Prior to treatment with **ReBalance Antiprotozoal Oral Suspension**, EPM should be distinguished from other diseases that may cause ataxia in horses. Injuries or lameness may also complicate the evaluation of an animal with EPM. In most instances, ataxia due to EPM is asymmetrical and affects the front and/or the hind limbs.

Treatment may cause generalized bone marrow suppression, anemia, leukopenia, neutropenia and thrombocytopenia. A complete blood count (CBC) should be performed monthly to monitor horses for development of these conditions. The administration of the drug may need to be discontinued and/or treatments for bone marrow suppression initiated.

Worsened neurologic deficits (treatment crisis) may be observed during a period beginning with the first few days of treatment with **ReBalance Antiprotozoal Oral Suspension** and ranging out to 5 weeks. This neurologic deficit exacerbation may be the result of an inflammatory reaction to the dying parasites in the CNS tissue.

The safe use of **ReBalance Antiprotozoal Oral Suspension** in horses used for breeding purposes, during pregnancy, or in lactating mares has not been evaluated. The safety of ReBalance Antiprotozoal Oral Suspension with concomitant therapies in horses has not been evaluated.

**ADVERSE REACTIONS:** Seventy-five horses (37 horses in the 1X group; 38 horses in the 2X group) that were treated with test article for at least 90 days were evaluated for adverse reactions.

**Bone marrow suppression:**

**Anemia: ReBalance Antiprotozoal Oral Suspension** administration caused overall anemia (classification of anemia based on RBC, Hgb, and PCV/HCT values) in 12% of the observations in the 1X group and 21% of the observations in the 2X group. In the 1X group, anemia was noted in 22%, leukopenia in 19%, neutropenia in 5%, and thrombocytopenia in 3% of the cases. In the 2X group, anemia was noted in 58%, leukopenia in 55%, neutropenia in 29% and thrombocytopenia in 5% of the cases. The incidence of bone marrow suppression in the 2X treatment group was two or more times that of the 1X group and the degree of suppression was more serious (mild to severe vs. mild to moderate). Because of these blood dyscrasias, test article was interrupted over four times more often in horses treated at the 2X dosage than those treated at 1X, although both groups were off treatment for about the same amount of time (approximately 20% of the treatment period). In some instances of bone marrow suppression, diet was supplemented with folinic acid.

**GI:** Anorexia was observed in two horses in the 1X group and one horse in the 2X group. One horse in the 1X group and one horse in the 2X group were observed to be off feed. Observations of anorexia and decreased appetite occurred predominantly during the first 90 days of the treatment period. Observations of anorexia/decreased appetite in two of the above-referenced cases were due to unrelated illnesses. Loose stools were observed in three horses in the 1X group and five in the 2X group. The majority of these observations occurred in the first thirty days of treatment.

Diarrhea was observed in one horse in the 2X group on Day 4 of the study. The appearance of loose stool/diarrhea observations was self-limiting and resolved without treatment or discontinuation of test article. Brief, mild colic was observed in three cases (one in the 1X group and two in the 2X group). Colic was treated conservatively or not at all and resolved without sequelae.

**Integument:** Urticaria was observed in one horse in the 1X group and two horses in the 2X group. One horse was treated topically, two were untreated. All cases resolved without sequelae.

**Treatment crisis:** (marked worsening of the neurological condition) was reported in one horse in the 1X treatment group.

**Depression/lethargy** was observed infrequently, occurred during the early part of the study in both groups and was primarily associated with the EPM syndrome. In one case, depression was associated with acute onset of a liver disorder.

**Seizure:** One horse in the 1X treatment group suffered from seizures. Seizure activity may be associated with CNS damage from EPM.

**CLINICAL PHARMACOLOGY:** Sulfonamides (a specific group of antimicrobial agents) and pyrimethamine are two different antimicrobial agents which inhibit folic acid synthesis at two different sites, in the same synthetic pathway. The combination of a sulfonamide and pyrimethamine is synergistic, with the drug combination having an antiprotozoal effect.

**EFFECTIVENESS SUMMARY:** A field effectiveness study was conducted at eight sites with eight investigators across the United States. The study was conducted using historical controls. In this study, each animal's response to treatment was compared to its pre-treatment values. The following standardized overall neurological dysfunction (OND) scale was used to grade the horses:

0 = Clinically normal. No detectable dysfunction.
1 = Slight deficit. Dysfunction barely perceptible.
2 = Moderate deficit. Dysfunction easily detectable.
3 = Marked deficit. Dysfunction strikingly conspicuous.
4 = Severe deficit. Profound dysfunction.
5 = Recumbent.

Ninety-seven horses were randomly assigned to one of two treatment groups and administered a daily oral dose of **ReBalance Antiprotozoal Oral Suspension** for a minimum of 90 days. The two treatment groups were as follows:

(1) 1X labeled dose, 20 mg/kg sulfadiazine and 1 mg/kg pyrimethamine (48 horses); or

(2) 2X dose, twice the labeled dose, 40 mg/kg sulfadiazine and 2 mg/kg pyrimethamine (49 horses).

A physical examination and neurological evaluation and complete blood profile were conducted at the end of each 30-day treatment period for the first 90 days of treatment.

At the end of the 90-day treatment period, a videotape recording of the neurological condition and CSF and serum sample immunoblot and protein electrophoresis analyses were made. Based on the degree of clinical improvement and results of the CSF immunoblot analysis on test day 90, treatment in 30-day increments up to a period of 180 days was continued. In fourteen cases, the treatment was extended beyond 180 days (up to 270 days). A 30-day follow-up evaluation was made following cessation of treatment.

Treatment success was defined as: (1) a horse that became CSF Western Blot Test negative with or without clinical improvement; and (2) a horse that remained CSF Western Blot Test positive but demonstrated marked clinical improvement (two or more grade improvement from baseline OND score).

Only the 1X dose was evaluated for effectiveness due to the toxicity (bone marrow suppression) seen at the 2X dose. Of the forty-eight horses assigned to the 1X group, 26 horses completed the study. Based on the improvement in the OND scores and/or a negative CSF immunoblot, 16 out of 26 horses (61.5%) were considered successes. Five of the 26 horses (19.2%), had a negative CSF immunoblot by day 150 of the study. Three of these five horses were also clinical successes based on the improvement in OND scores. Fourteen of the 26 horses (53.8%) were corroborated as successes by masked expert evaluation of videotapes.

**ANIMAL SAFETY: ReBalance Antiprotozoal Oral Suspension** was administered to ten horses (5 males and 5 females) at a dosage of 8 mL/50 kg (110 lbs) a day (2X the labeled dose) for 92 days. Four horses (2 males and 2 females) were untreated controls.

Complete physical examinations, CBCs and serum chemistry values were determined on test day (TD) minus 14, TD minus 7, TD 0, biweekly throughout the 92 day treatment period and 14 and 29 days following the end of treatment.

Declines in RBC, HCT, Hgb and PCV were greater in the treated group and reached statistical significance. Twenty-nine days after cessation of treatment, blood parameter values returned to baseline levels. No clinical signs of anemia were observed in either group.

Most serum chemistry values remained within normal limits throughout the study in both groups. Alkaline phosphatase (ALP) values were evaluated (slightly above the upper end of the normal range) in three treated horses on study days 84 and 105.

Loose stools, along with infrequent diarrhea, were noted in the treatment group. The conditions were transient and required no medical intervention.

A depressed appetite of 1 to 2 days duration occurred infrequently in all but one of the treated horses. One horse became anorexic and required a change in diet.

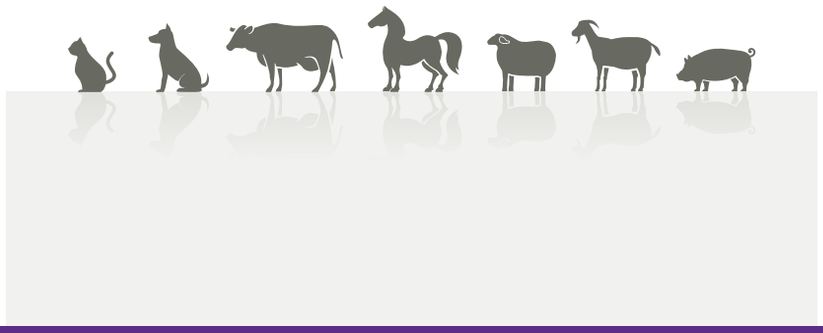
**ReBalance Antiprotozoal Oral Suspension** administered at 2X the recommended label dose for 92 days resulted in clinical signs of toxicity including transient anemia and loose stools; however, medical intervention was not necessary.

**STORAGE:** Store at 20°C-25°C (68°F-77°F), excursions permitted between 15°C-30°C (59°F-86°F).Protect from freezing.

**HOW SUPPLIED:** Each mL of **ReBalance Antiprotozoal Oral Suspension** contains 250 mg sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine and is available in 946.4 mL (1 quart), multiple dose, child-resistant, screw-capped bottles.

For a Material Safety Data Sheet (MSDS) or to report Adverse Reactions, call Pegasus Laboratories, Inc. at 1-800-874-9764.

**Manufactured by:**
Pegasus Laboratories, Inc., An Employee-Owned Company, Pensacola, FL 32514, USA



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