ReBalance®
(Sulfadiazine and Pyrimethamine)
Antiprotozoal Oral Suspension

Duralactin®

EQUINE ESSENTIALS

PRN® PHARMACAL

FOR THE HEALTH OF YOUR HORSE

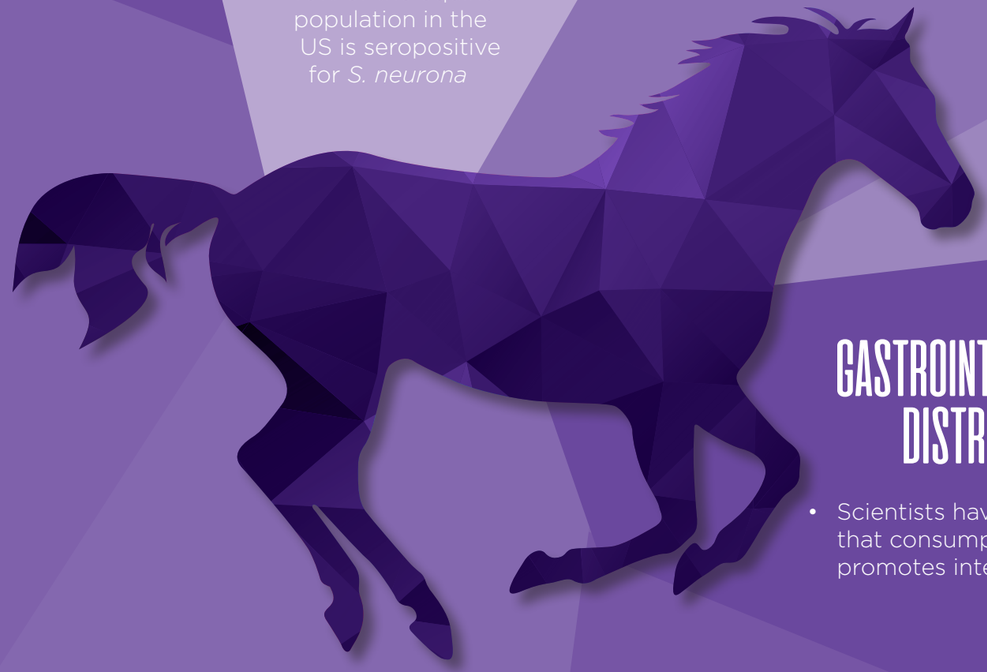
PRN Pharmacal Equine Products — For the Health of Your Horse

EPM

- Only 3 drug formulations are FDA-approved for use in controlling EPM infections
- Studies show that 40% of the equine population in the US is seropositive for *S. neurona*

SUTURES

- Surgeon's choice of suture is based on handling characteristics, tensile strength, knot security, and absorption rate



GASTROINTESTINAL DISTRESS

- Scientists have shown that consumption of clay promotes internal healing

WOUND HEALING

- Topical treatment with silver-based dressings helps reduce microbial growth
- Collagen promotes granulation tissue formation and epithelialization of wounds
- Careful debridement is the first step to successful wound healing

FLY OINTMENT

- Application of repellent around wounds can minimize the risk of infection and promote healing

Data on file

PRN® PHARMACAL

PRN Pharmacal focuses on arming veterinarians, animal caregivers, and the animal health industry with a range of tools — therapeutics, nutraceuticals, and medical supplies — that allow them to treat diseases and conditions that impact the quality of life for animals and their owners. Our research and development places products for underserved categories of diseases and conditions within the reach of veterinarians, removing barriers to effective, reliable treatment options.

ReBalance®

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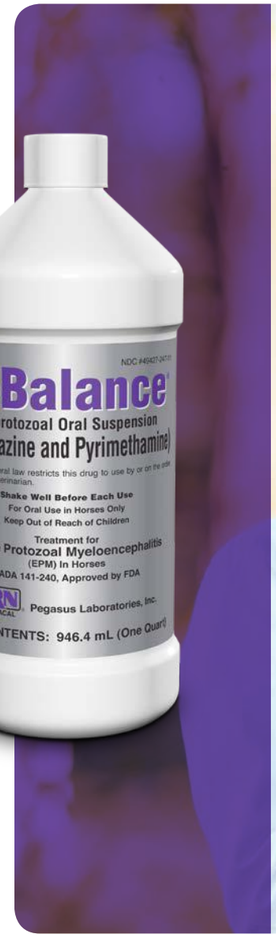
(Sulfadiazine and Pyrimethamine)

Antiprotozoal Oral Suspension



The challenge of EPM

Equine protozoal myeloencephalitis (EPM) is a common, progressive neurological disease found in horses in North and South America.

- Often caused by ingestion of *sarcocystis neurona* in food or water
- Contamination comes from the waste of infected opossums
- Symptoms often mimic other neurological diseases
- Diagnosis is expensive and difficult to diagnose
- Due to the lack of a vaccine or other preventative treatment, early intervention is crucial
- Untreated EPM can cause death

Treatment of EPM with ReBalance® (sulfadiazine and pyrimethamine) Antiprotozoal Oral Suspension

ReBalance oral suspension is one of three FDA-approved commercially available treatments for EPM, and the only approved sulfadiazine-pyrimethamine combination. While all three treatments are similar in safety and effectiveness, ReBalance treatment costs up to 1/3 less than the other options.[2] And 61.5% of treated horses responded positively to the product.[3]

ReBalance treatment costs up to 1/3 less than the other options.

FDA approval indicates consistent quality standards, proven efficacy of the drug and ongoing safety reporting. Compounded medications are not evaluated by the FDA and may not meet FDA standards for safety and effectiveness. In general, the FDA has serious concerns about unapproved animal drugs, including certain compounded drugs. Unapproved drugs also may not be labeled or advertised appropriately. Please consult your veterinarian about other treatments.[4]

Effective treatment, proven by research

Only the 1X dose was evaluated for effectiveness due to the toxicity (bone marrow suppression) seen at the 2X dose. Of the 48 horses assigned to the 1X group, 26 horses completed the study. Based on the improvement in the Overall Neurological Dysfunction (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.[3]

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.

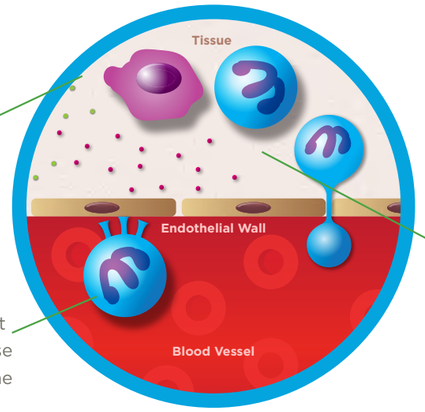
Duralactin® Products

The newest products in our equine portfolio, Duralactin®, are not new at all. This nutritional supplement contains MicroLactin® which has been proven effective in multiple animal species.[1] Recent studies show that MicroLactin helps manage the clinical signs of inflammation in equine patients as well.[5]

Only Duralactin contains MicroLactin®, a milk-based protein that helps reduce inflammation at the cellular level. Unlike other products that are characterized as "joint health supplements," Duralactin products can be a valued addition to your treatment protocols for horses with joint issues and other inflammatory conditions.

Managing inflammation at the source

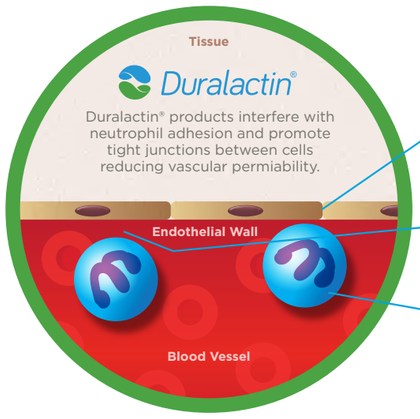
Inflammation is the body's normal response to damaged tissue and the presence of harmful organisms.



Neutrophils, the white blood cells that the body uses to fight infection, release substances to destroy the source of the infection and tissue damage.

While the function of neutrophils is important to recovery from infection, the cells can also attack healthy tissue, leading to chronic inflammation and pain.

How MicroLactin® works:



It blocks the entry of neutrophils from the circulatory system into the site of tissue damage. This is achieved by helping maintain tight cell junctions.[6]

It inhibits and reverses neutrophils from attaching to the endothelial wall.[7,8,9] This is done via its effects on the CD18 Glycoprotein complex on the surface of the neutrophil.

As a result, neutrophils remain in the bloodstream and do not increase inflammation.

MicroLactin also helps maintain the proper action of macrophages,[10] cells that form in response to inflammation, and help build the immune response.

MicroLactin: The Duralactin Difference

MicroLactin is extracted from dairy cows using hyperimmunization, a process that stimulates production of the hyperimmune milk factor (HIMF) in cows. Duralactin contains a concentrate of HIMF.

The benefits of Duralactin:

- You can utilize Duralactin as a primary supplement or an adjunct to other therapies.
- You can use Duralactin with both young and old horses that have been diagnosed with inflammation, or as a supplement to support normal activity and wellness.
- Duralactin does not have the side effects associated with other treatments, and it is tolerated in high-risk patients.
- Horses readily accept Duralactin pellets, making administration easy.

HIMF can both prevent and treat inflammation[9,11]

The results of treatment with Duralactin: research studies

MicroLactin and Equine Inflammation[5]
Method: 58 horses exhibited inflammation from the following causes:
- skin, muscle, foot and joint trauma
- gastrointestinal, respiratory and soft tissue toxins
- respiratory and dermatologic allergic reactions
- dermatologic and neurologic infections

"An oral supplement containing 7,000 mg MicroLactin was given twice daily (14,000 mg per day)"

Results:
- Inflammation reduced in 86% of patients (44/51)
- "Satisfied owners continued MicroLactin in horses with respiratory, dermatologic and musculoskeletal inflammation"

Duralactin is available as a tablet, soft chews, capsules, and paste for other species.

Visit ***DURALACTIN.COM*** for more information.

Disinfectants and Wound Care

Collasate® Family - Postoperative Topical Dressing
For management of postoperative and trauma sites

- With Type I Hydrolyzed Collagen, a revolutionary, patented wound healing collagen
  - Provides healing benefits of collagen in form immediately available to the body
  - Absorbs bacterial and debris exudate (ooze)
  - Forms occlusive barrier to maintain temperature and moisture balance
- Tissue-adhesive properties seal and protect the wound
- Nutritive protein supplied directly to the wound
- Dressing changes are simple and non-invasive

Collasate Silver contains Silver Oxide to help minimize infection

Storage and Safety:

- Store at room temperature 15°-30° C (59°-86° F).
- Keep from freezing. Extreme temperatures may affect viscosity but will not affect product performance.
- Keep out of reach of children and pets.
- Use only as directed.
- If condition worsens or does not improve within 10-14 days, contact your veterinarian.

Collasate Spray - Avoid contact with mouth and nose, as Bitrex is very bitter. Avoid contact with the eyes as the Bitrex may cause eye irritation.

Xenodine™ Polyhydroxydine™ Solution
Topical antiseptic solution

- Penetrates the skin without dermal toxicity
- Aids healing of wounds, cuts, and abrasions; ears; hooves; castration; ear and tail cropping; surgical site preparation
- Helps prevent topical bacterial and fungal infections
- Active Ingredient: Iodine (1%)

Suture Products

Monomend® MaX Absorbable Sutures
Wound closure security for patients with compromised wounds

- Long-term synthetic absorbable poly-p-dioxanone monofilament suture
- Superior strength retention for gentle and extended wound support
- Retains 50% of knot tensile strength after 28-35 days
- Complete mass absorption in 180-210 days
- Excellent pliability, supple and easy to knot
- Smooth tissue passage
- 27” in length
- Packaged 1 dozen per box

Monomend® MT Absorbable Sutures
Stability and patient comfort for typical wound healing

- Glyconate structure causes low tissue reaction and helps reduce patient discomfort.
- Mid-term synthetic absorbable monofilament suture made of glyconate
- 50% retention of knot tensile strength up to 14 days
- Complete mass absorption in 60-90 days
- Secure knotting performance
- Easy tissue passage
- Excellent pliability
- 36” in length, except Y463, Y844 and Y464, which are 18”
- Packaged 1 dozen per box

Polymend® MT Absorbable Sutures
Braided sutures with predictable and reliable absorption

- Mid-term synthetic absorbable 90/10 Poly (glycolide-co-L-lactide) coated, braided suture
- Easy handling and excellent knot security
- Degrade by hydrolysis
- Holds through the critical wound healing period and then is rapidly absorbed
- Retains 50% of knot tensile strength at 21 days
- Complete mass absorption in 56-70 days
- Smooth knot run down
- 27” in length
- Packaged 1 dozen per box

NY-STĀ® Non-Absorbable Sutures
Sutures for secure and tightly held knots

- Non-absorbable nylon monofilament suture
- High knot pull tensile strength
- Premium knot holding ability
- Smooth surface for easy tissue passage
- Packaged 1 dozen per box

Endosorb® Suspension

Absorbent Anti-Diarrheal Demulcent

Gastrointestinal distress. Even though antibiotics can help when the problem is due to infection, they also can interfere with gastrointestinal tract healing.

Endosorb Suspension absorbs toxins for symptom relief.

- Contains attapulgite — a natural clay absorbent
  - Helps body eliminate diarrhea-causing bacteria
  - Improves stool consistency
- Relieves irritation, discomfort, and cramping from diarrhea
- Antibiotic-free
- Citrus pectin coats the intestinal tract
- Carob pulp adds soothing bulk to the stool
- Magnesium and aluminum silicate act as a gastric antacid

The Endosorb advantage

Endosorb is a low-cost treatment that helps relieve the discomfort of diarrhea and gastrointestinal disturbances in horses. It is available in tablet, bolus, and liquid, flavored suspension formulations for convenient dosing of adult horses as well as colts.

Endosorb Suspension is available for Equine. Endosorb bolus and tablets are available for other species.

Storage and Safety:

- Store in a cool, dry place
- Keep out of reach of children and pets
- For veterinarian use only
- Not for human use
- Use only as directed

Liqui-Tinic™ 4X

Flavored Vitamin and Iron Supplement

Provides vital nutrients for horses recovering from illness or infection, or with special dietary needs

- Delivers iron, B-complex vitamins, and amino acids in a palatable liquid formulation
- Promotes healthy appetite
- Helps correct nutritional deficiencies
- Easy-to-administer
- Low cost

Storage and Safety:

- For oral use only
- Keep out of reach of children and pets
- For veterinarian use only

Vet-Kem® Clear Fly Repellent Ointment

Clear ointment repels:

- houseflies
- stable flies
- face flies
- horn flies

ReBalance®

(Sulfadiazine and Pyrimethamine)

Antiprotozoal Oral Suspension

Shake Well Before Each Use

For Oral Use in Horses Only
Keep Out of Reach of Children

Treatment for Equine Protozoal Myeloencephalitis (EPM) In Horses

NADA 141-240, Approved by FDA

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 sulfa diazine 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 Anti protozoal 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.tObservations 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 Anti protozoal Oral Suspension c**ontains 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.

U.S. Patent No. 5,747,476; 6,255,308 and 6,448,252

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Manufactured by:

Pegasus Laboratories, Inc.

An Employee-Owned Company
Pensacola, FL 32514, USA

NDC #49427-247-11 1-2012

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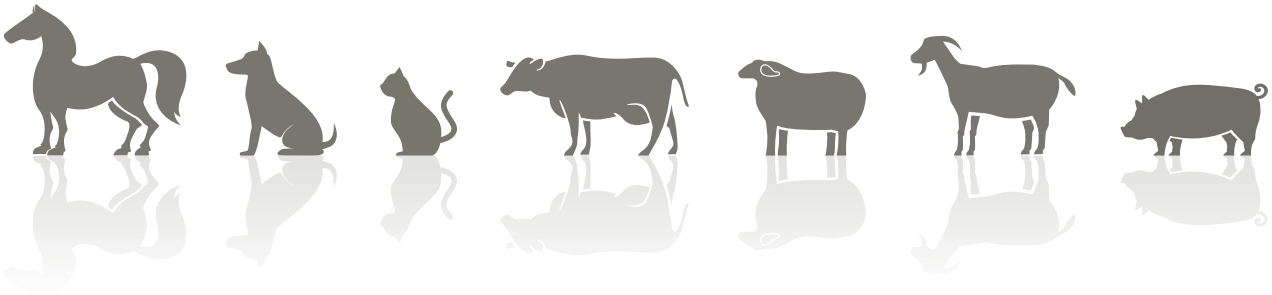
Innovative products for equine health.

For more information on the PRN portfolio of products, contact your PRN Pharmacal Representative.

Duralactin® products have not been approved by the FDA nor is it intended to diagnose, treat, cure or prevent any disease. Should only be used through consultation of a veterinarian and in conjunction with an overall wellness program.

PRN® Pharmacal, an employee-owned company, has been dedicated to developing specialized therapeutics that address the unmet, underserved and overlooked needs of the veterinary medicine community since 1978. Our commitment: quality solutions - as needed, when needed.



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