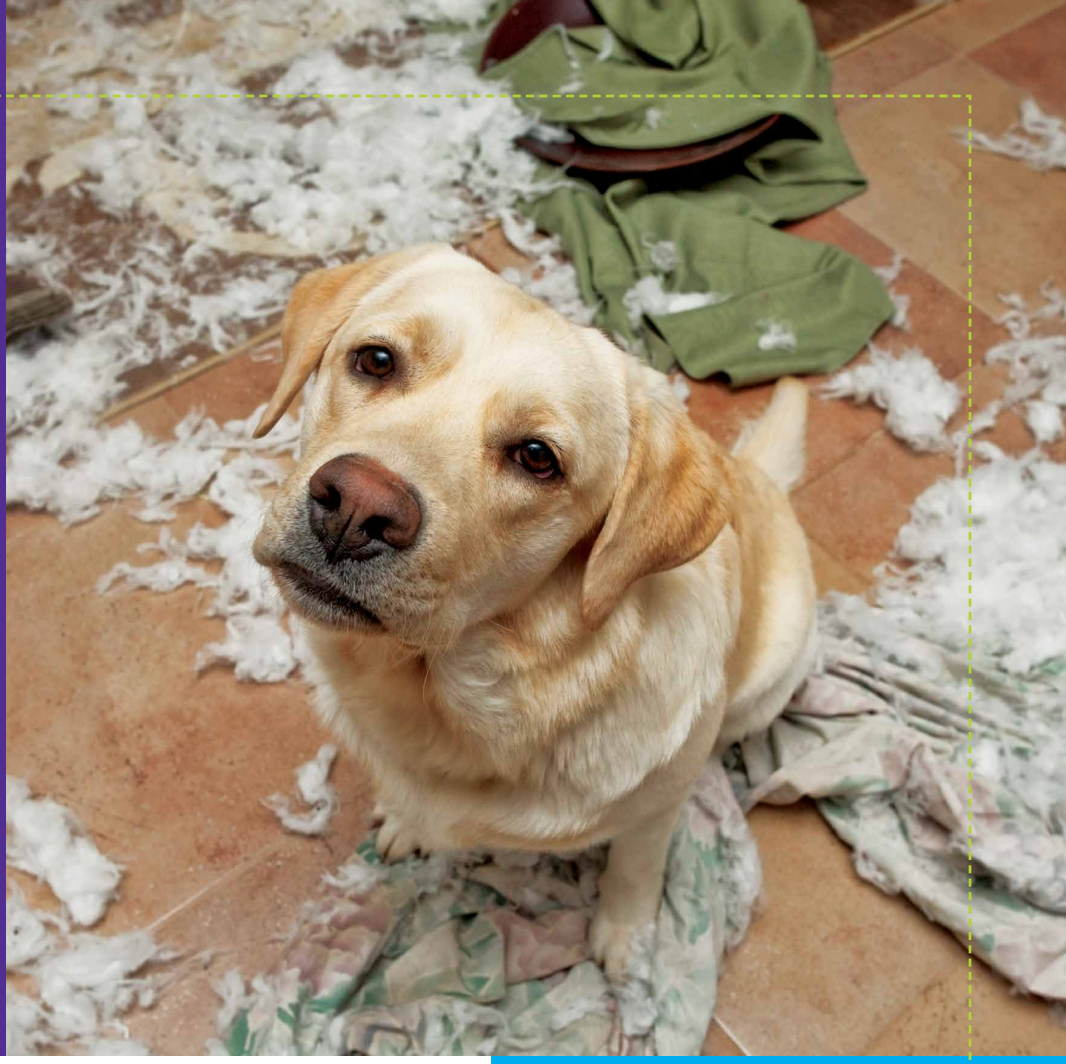

To the anxious dog a few minutes can seem like eternity
Trusted help is back in your hands
Reconcile®
(fluoxetine hydrochloride)
PRN™
PHARMACAL

SEPARATION ANXIETY— the second most common canine behavioral condition[1]



Dogs are by nature social animals that bond readily with family members. When separated from their owners, this departure may trigger problematic behavior known as separation anxiety.[2]

An estimated 14% to 17% of dogs are affected by separation anxiety[3,4]

Of dogs relinquished to animal shelters, 40% have at least one behavioral issue[5]

BEHAVIOR

A dog with separation anxiety may exhibit excessive behaviors,[6] such as:

Separation anxiety can develop at any age in either sex and has been diagnosed in all breeds

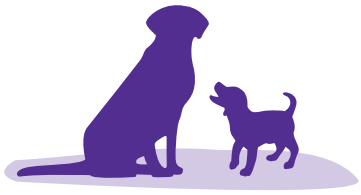
Usually, negative behaviors occur within 10 to 30 minutes of the owner's departure, and bouts of rest alternating with barking and destructive behavior every 40 to 60 minutes.[2,7,8]

The owner of a dog with separation anxiety needs to understand that the dog is not being spiteful.

Unfortunately, the destructive behaviors can result in damage to the owner's property, self-injury to the dog and disruption of the human-animal bond.[7] These are all common reasons why owners choose to relinquish or euthanize their dogs.[2]

What are the potential risk factors?

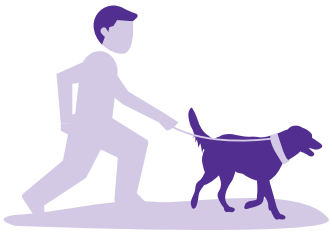
A definitive answer has not been identified, but potential triggers include[2–4, 8,9]:



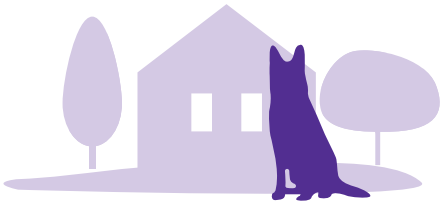
Inherited predisposition

Limited early experiences

Noise/storm sensitivities



Changes in the owner's work schedule or daily routine



Moving to a different residence

New owner or family

Aging and decline of cognition

Alteration of the family structure through birth or death

How is separation anxiety diagnosed?

For dogs that show uncharacteristic behaviors a thorough history is essential. The history should include screening for aggression as well as questions about additional fears or phobias.[7]

Laboratory tests, such as a complete blood cell count, biochemistry, thyroid test, and urinalysis, may be appropriate to determine other potential underlying causes of the behavior.

A dog with separation anxiety is not a hopeless case. When it is clear that the behaviors are not caused by a physical problem, using a behavior treatment plan that includes medication can help the affected dog become less anxious and more relaxed in the owner's absence.[6]

A dog that is showing any signs of separation anxiety should be examined by a veterinarian to rule out other possible underlying conditions

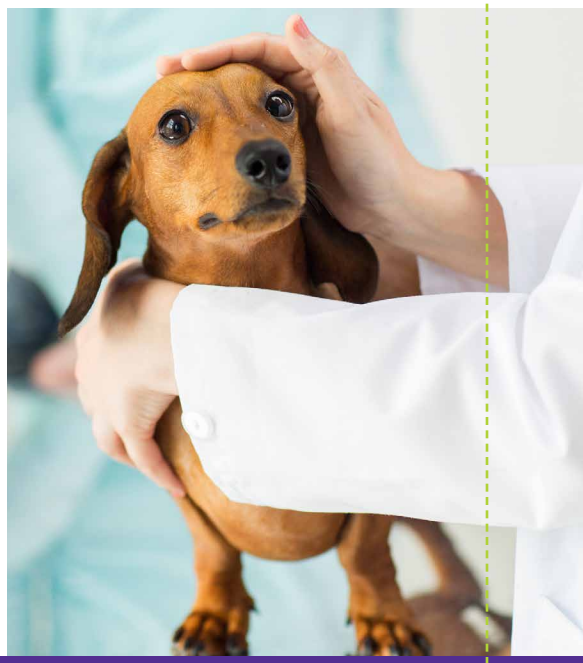
Introducing Reconcile® (fluoxetine hydrochloride) again

Reconcile®, a flavored, chewable tablet that contains fluoxetine hydrochloride, was developed specifically for dogs with separation anxiety and is available again from a trusted manufacturer.

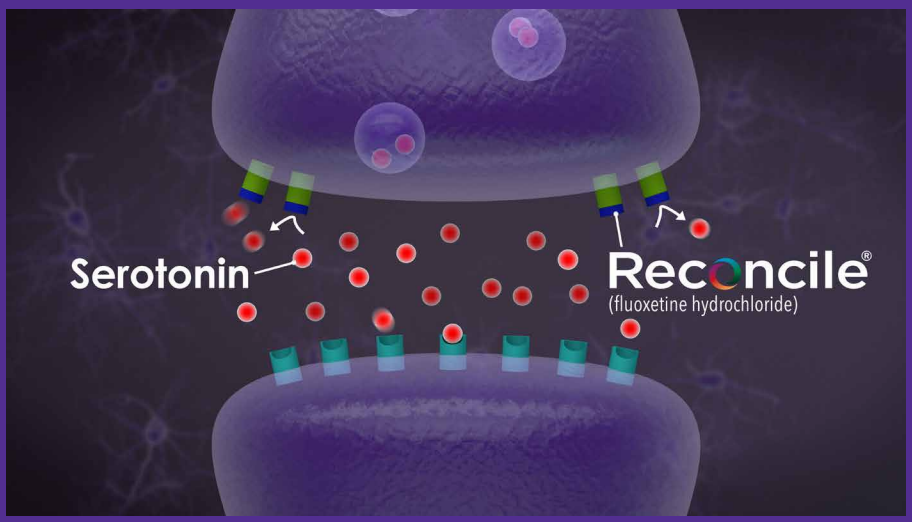
Reconcile chewable tablets are FDA approved for the treatment of canine separation anxiety in conjunction with a behavior modification plan directed by a veterinarian and carried out by the pet's owner.

How does Reconcile work?

Neurotransmitters, such as serotonin, are released from the presynaptic neuron and attach to receptors on the postsynaptic site. They are then reabsorbed back into the presynaptic site. Research has shown that control of anxiety is one function of serotonin. Reconcile, a selective serotonin reuptake inhibitor (SSRI), helps correct the imbalance by blocking the reuptake of serotonin and temporarily increasing the level in the synapse.



Mode of Action



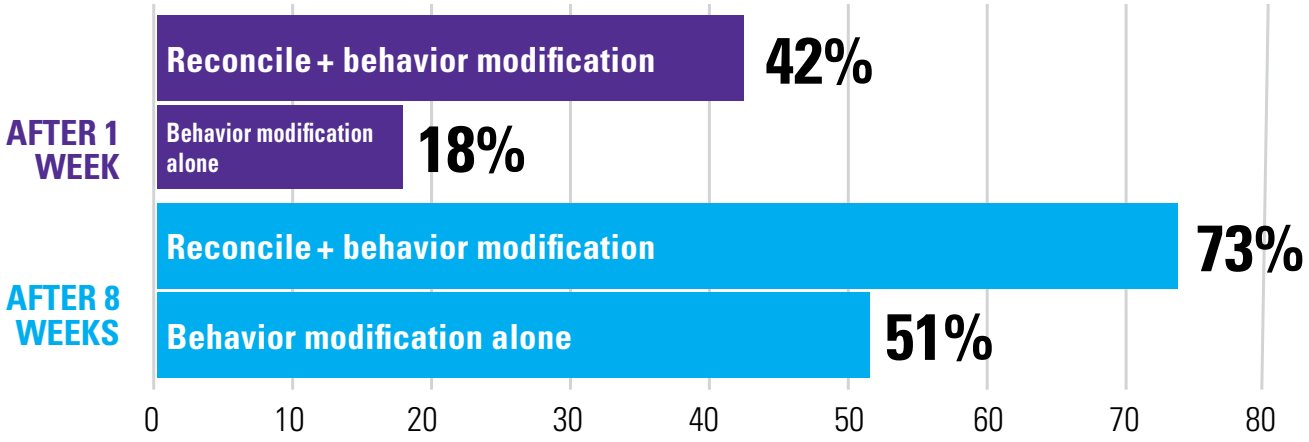
Reconcile achieves a calmer frame of mind in dogs, reducing detrimental behaviors and making them more receptive to training

How well does Reconcile® work?

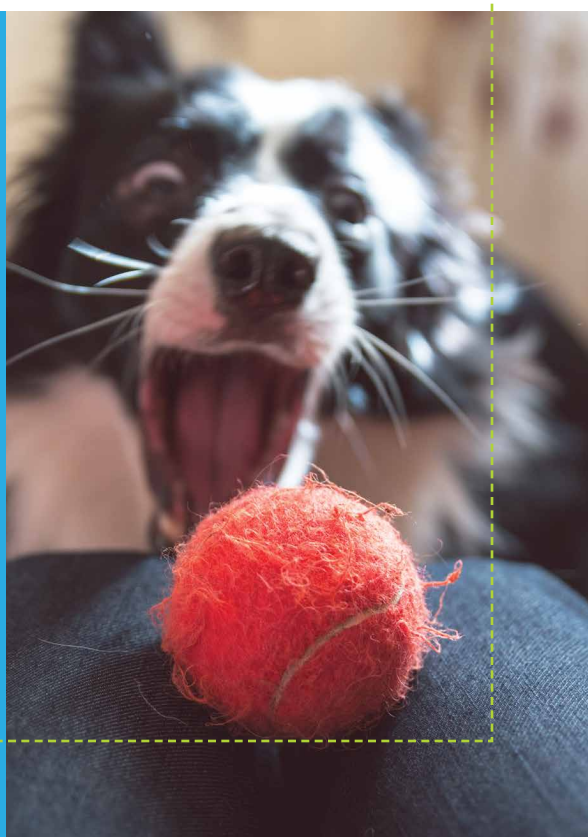
A multicentered, double-blinded study was conducted in 229 dogs for 70 days, with dosing of participating dogs for 56 days (14 days pretreatment), to compare the Reconcile® chewable tablet to a placebo control tablet.[11] Both groups received behavior modification training. After 1 week, significantly more dogs receiving Reconcile had measurable improvement. After 8 weeks, 73% of dogs receiving Reconcile had measurable improvement compared to just over half of those receiving only placebo control tablets.

As Reconcile is indicated for treatment of separation anxiety in dogs only in conjunction with a behavior modification plan, the simple but essential steps involved in BOND™ training are described on page 8.

Efficacy data



Results of clinical trials showed that after 8 weeks 73% of dogs receiving Reconcile *and* behavior modification training combined had significant behavioral improvement, compared with only 51% of dogs receiving behavior modification training alone



Is Reconcile® safe?

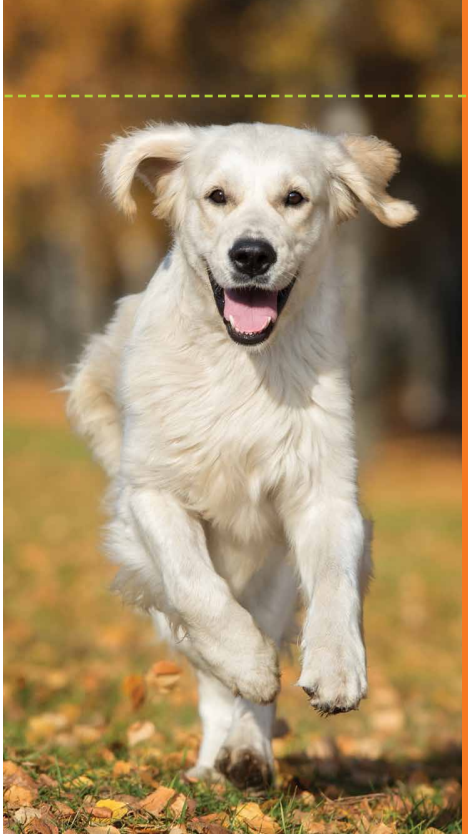
Reconcile® is approved only for use in dogs and must be prescribed by a veterinarian. Studies demonstrate that Reconcile has proven safe when prescribed and used as directed.

In a double-blinded, laboratory safety study, 38 dogs were administered Reconcile for one year at 0.5×, 2.25× and 10× the recommended treatment dose to determine the potential cumulative toxicity and reversibility of any toxicologic effects of fluoxetine hydrochloride with chronic administration to Beagle dogs.[10]

The study demonstrated that fluoxetine has a variable, individual safety response regarding reported adverse events. As with all drugs, it is important to monitor closely for any side effects to ensure dosing accuracy. The most common adverse events reported in decreasing order of reported frequency are noted in the box at right.

Reconcile is contraindicated for use in dogs with a history of seizures and should not be given to aggressive dogs, nor should the drug be given to dogs with a known hypersensitivity to SSRIs or fluoxetine hydrochloride.

Note that Reconcile has not been clinically tested for the treatment of other behavioral disorders or for use in breeding, pregnant or lactating dogs. Administration to dogs less than 6 months of age has not been studied. See the package insert that appears on pages 10–11 for more information.



Reconcile is safe for dogs, producing measurable improvement when used as prescribed

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 pages 10-11.

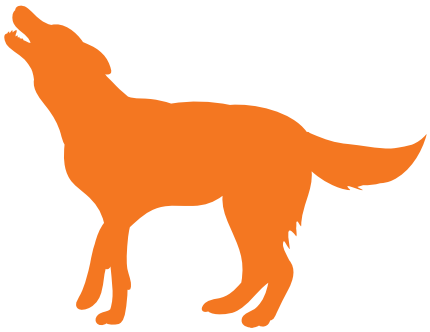
BOND™: A simple behavior modification plan

Behavior modification training is an important part of managing separation anxiety in dogs. The BOND™ program was designed to help pet owners train their dogs by executing simple and easy-to-understand steps.

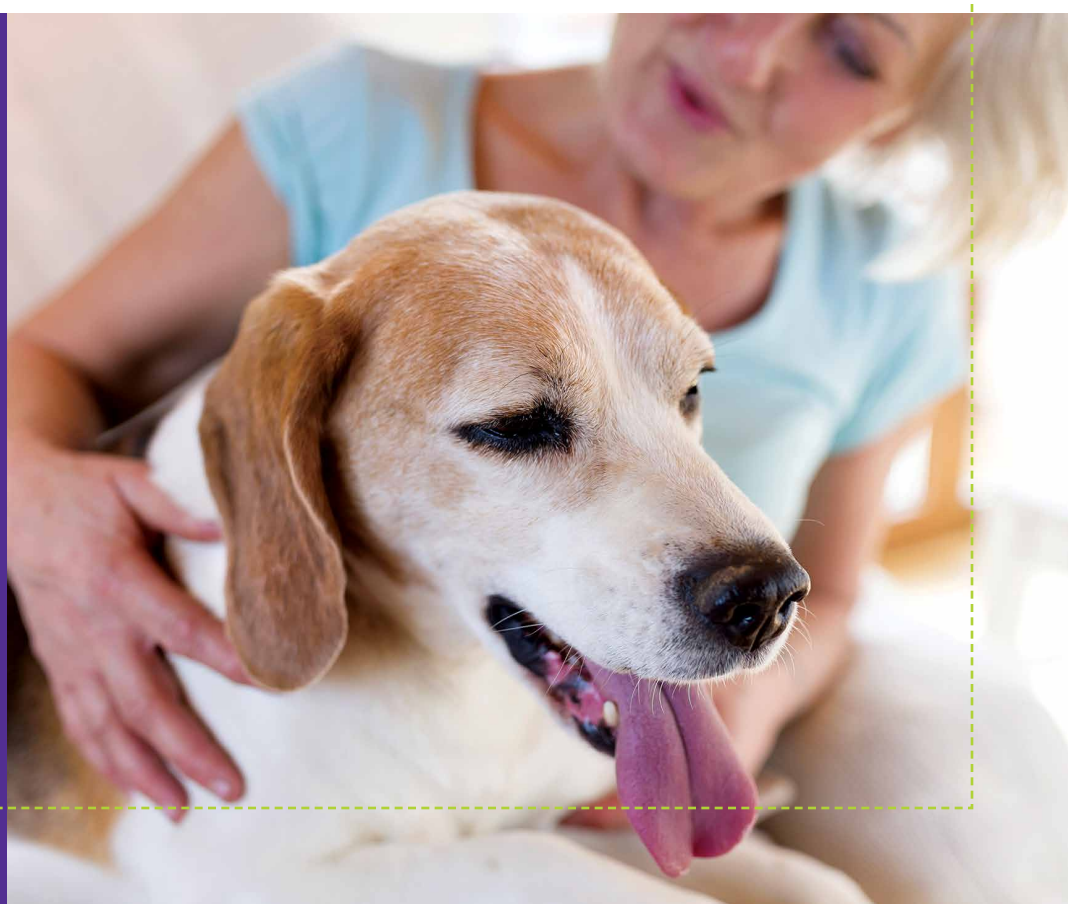
PRN Pharmacal has created several tools to help veterinarians educate pet owners about behavior modification, including a training video available at **Reconcile.com**.

The video features a detailed walk-through that clearly illustrates the four BOND training steps (see information above).

1. **Be Positive**
   Focus on positive behaviors and reward them. Don't reprimand past behaviors.
2. **Only Reward Calm Behavior**
   Ignore attention-seeking, spend relaxed time with the dog only when the dog is calm, and include active time daily.
3. **No More Drama When You Come and Go**
   Change departure patterns, distract the dog before leaving, go out without fanfare, and wait for calm upon returning.
4. **Develop Your Dog's Independence**
   Teach the dog to relax while you are gone, establish a safe place the dog recognizes, increase separation periods, and reward calm behavior.



73% of dogs with separation anxiety showed measurable improvement in 8 weeks when Reconcile® was used with BOND training



References

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5. Salman MoD, Hutchison J, Ruch-Gallie R, et al. Behavioral reasons for relinquishment of dogs and cats to 12 shelters. *J Appl Anim Welfare Sci*. 2000;3(2):95.
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11. Elanco Animal Health. Field study T8E420001. Efficacy Evaluation of Fluoxetine (fluoxetine hydrochloride) for the Control of Separation Anxiety in Dogs. Freedom of Information Summary NADA 141-272; Reconcile Fluoxetine Hydrochloride Chewable Tablets: Dogs. 2007: 3.

For details and a step-by-step video about the BOND™ behavior modification training program, go to Reconcile.com

Why choose Reconcile®?

The renewed availability of Reconcile® enables veterinarians to manage separation anxiety with a tried-and-true chewable medication that appeals to the affected dogs and is easily dosed by their owners.

Compare Reconcile to human generic alternatives:

Feature	Reconcile	Human generic alternatives
Flavored, chewable, once-a-day tablet	✓	✗
Clinically tested and FDA approved for use in dogs	✓	✗
Four convenient strengths: 8 mg, 16 mg, 32 mg and 64 mg	✓	✗
Exclusive behavior modification plan	✓	✗
Clinic and pet owner educational materials	✓	✗
Product support services	✓	✗

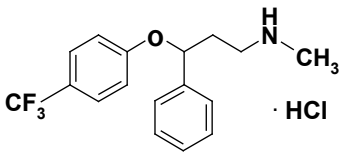
Reconcile is manufactured in PRN™ Pharmacal's advanced production facility, Pegasus Laboratories, located in Pensacola, Florida, according to the strictest current good manufacturing standards. Premium ingredients are used because quality is the company's #1 priority for pets. This ensures a reliable supply of responsibly manufactured, efficacious product.

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, ketoconazole). 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

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

Reconcile®

(fluoxetine hydrochloride)

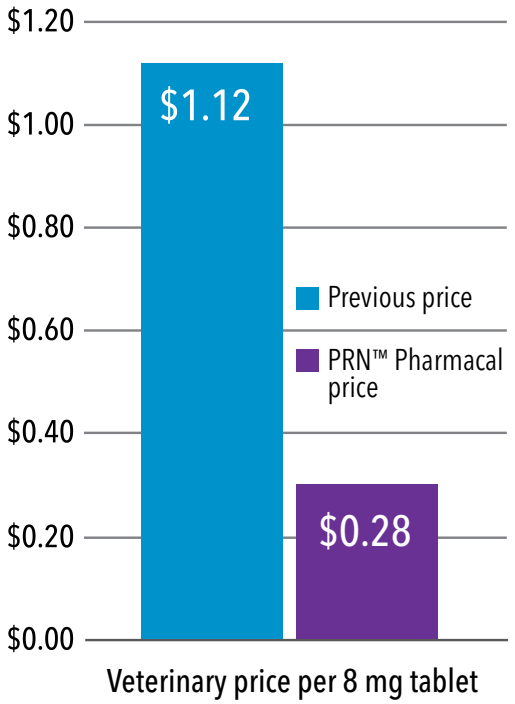
Product Highlights

- **ONCE-A-DAY, FLAVORED, CHEWABLE TABLET—highly appealing and easy to administer**
- **FDA APPROVED FOR USE IN DOGS in conjunction with a behavior modification plan**
- **AFFORDABLE for veterinarians to stock and pet owners to purchase—priced considerably lower than when previously on the market**
- **REDUCES STRESS FOR BOTH PET AND OWNER, strengthening the human-animal bond**
- **VETERINARY-EXCLUSIVE FORMULATION**

Recommended dose of Reconcile® chewable tablets: 1 - 2 mg/kg.

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

Reconcile® is now priced 75% lower than when previously marketed



CONTENT AND VIDEO SUPPORT for pet owners always available at

Reconcile.com

PRN™ PHARMACAL

As an employee-owned company, we have been dedicated to developing specialized therapeutics since 1978.

8809 Ely Road, Pensacola, FL 32514
800.874.9764

prnpharmacal.com/reconcile

Reconcile® chewable tablets are indicated for the treatment of canine separation anxiety in conjunction with a behavior modification plan. Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

PRN is a trademark and Reconcile is a registered trademark of Pegasus Laboratories, Inc.

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