



Be Part of the Solution: A Simple Behavior Modification Plan for Your Dog with Separation Anxiety

Your doctor has prescribed **Reconcile**® (fluoxetine hydrochloride) to treat separation anxiety in your dog in conjunction with a behavior modification plan. The **BOND**™ training program will help your dog build confidence and a sense of security when home alone.

BOND™

1 Be Positive

Focusing on positive behaviors is critical to success.

- Reward your dog with a tummy rub, a tasty treat or a toy when they show calm and relaxed behavior.
- Do not reprimand undesired behaviors that happen when you're away, including past inappropriate behaviors.

2 Only Reward Calm Behavior

Ignore attention-seeking behaviors and reinforce calm behaviors.

- Look for opportunities to spend relaxed time with your dog, such as cuddling on the couch.
- Spend time with your dog only when he is calm.
- Include daily walks and play time in your schedule whenever possible.

3 No More Drama When You Come And Go

Grabbing your keys or coat can be a signal that creates anxiety, resulting in undesired behaviors.

- **When You're at Home:** Prepare to leave when you're not going anywhere. Grab your keys, put on your coat, walk to the door but then return to your previous activity.
- **When You Leave:** 20-30 minutes before going out, give your dog a favorite distraction (toy or treat). Ignore your dog until it's time to leave, then simply walk out without speaking to or giving your dog any attention.
- **When You Return:** Ignore your dog until he calms down and then reinforce this positive behavior.

4 Develop Your Dog's Independence

Help your dog learn to relax while you're away.

- Provide a "safe place," such as a small rug, for your dog to be calm; teach him to settle and stay there for increasing periods of time.
- Gradually increase time and distance separating you from your dog and follow recommendations from steps #1 and #2 to reward calm behavior.



Reconcile®
(fluoxetine hydrochloride)
Affordable. Reliable. Chewable.

To learn more about **Reconcile**® or the **BOND** behavior modification training plan and to download a journal template to monitor your dog's progress, visit Reconcile.com.

RECONCILE® (fluoxetine hydrochloride) Chewable Tablets

For complete prescribing information, see full package insert. **Caution:** Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Indications: RECONCILE chewable tablets are indicated for the treatment of canine separation anxiety in conjunction with a behavior modification plan. **Contraindications:** RECONCILE chewable tablets should not be used in dogs with epilepsy or history of seizures, nor given concomitantly with drugs that lower the seizure threshold (e.g., phenothiazines). RECONCILE chewable tablets should not be given in combination with, or within 14 days of discontinuing, a monoamine oxidase inhibitor (MAOI). RECONCILE chewable tablets are contraindicated in dogs with a known hypersensitivity to fluoxetine HCl or other SSRIs. • Observe a 6-week washout interval following discontinuation of therapy with RECONCILE chewable tablets prior to the administration of any drug that may adversely interact with fluoxetine or its metabolite, norfluoxetine. **Human Warnings:** Not for use in humans. Keep out of reach of children. In case of accidental ingestion seek medical attention immediately. **Precautions:** RECONCILE chewable tablets are not recommended for the treatment of aggression and have not been clinically tested for the treatment of other behavioral disorders. Studies 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. • RECONCILE chewable tablets have not been evaluated with drugs that affect the cytochrome P450 enzyme system and should be used with caution when co-administered with any drug that affects this system. Studies to assess the interaction of RECONCILE chewable tablets with tricyclic antidepressants (TCAs) (e.g., amitriptyline, clomipramine) have not been conducted. The minimum washout period to transition dogs from TCAs to RECONCILE chewable tablets has not been evaluated. Data demonstrate that TCAs are cleared 4 days following discontinuation.^{1,2} **Adverse Reactions:** In two North American field studies involving 427 dogs, the following adverse reactions were observed at a rate of $\geq 1\%$ in dogs treated with RECONCILE chewable tablets (n=216): calm/lethargy/depression (32.9%), decreased appetite (26.9%), vomiting (17.1%), shaking/shivering/tremor (11.1%), diarrhea (9.7%), restlessness (7.4%), excessive vocalization (including whining) (6.0%), aggression (4.2%), otitis externa (2.8%), disorientation (2.3%), incoordination (2.3%), constipation (1.4%) and excessive salivation (1.4%).

Other adverse reactions: Seizures: 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 during or after the end of the treatment period. One dog that was treated with RECONCILE chewable tablets experienced two seizures 10 days after the end of therapy and, despite escalating phenobarbital doses, died in status epilepticus approximately six months after the first seizure. 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. • Lastly, in a European multi-site study, one dog treated with a daily dose of 0.4 mg/kg for one month experienced one seizure one week after discontinuing therapy. **Weight loss:** In field studies, a weight loss $\geq 5\%$ (relative to pre-study body weight) was observed in 58 (29.6%) of dogs treated with RECONCILE chewable tablets and 24 (13.0%) of control dogs. No dogs were withdrawn from clinical studies due to weight loss alone. **Dose reduction:** Twenty dogs in the RECONCILE chewable tablet group and five control dogs required a dose reduction due to unacceptable adverse reactions, the majority intermittent and mild, generally anorexia, vomiting, shaking and depression. Lowering the dose eliminated or reduced the severity of these reactions in the RECONCILE chewable tablet group only, while resumption of the full dose resulted in a return of the initial adverse reactions in approximately half the affected dogs. One dog experienced recurrence of severe adverse reactions, which necessitated withdrawal from the study. • Additionally, two dogs required a second dose reduction of RECONCILE chewable tablets. **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-FDAVETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>. **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.

To obtain full product information please call 800-874-9764 or visit Reconcile.com.

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NADA #141-272 Approved by FDA

Pegasus Laboratories, Inc.

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.

Dosage and Administration: For use in dogs only. The recommended dose of Reconcile chewable tablets is 1-2 mg/kg administered once daily, in conjunction with a behavior modification plan. Storage: Store at 20-25° C (68-77° F), excursions permitted between 15-30° C (59-86° F). Do not remove desiccant from bottle. Completely close bottle between uses. **WARNINGS: NOT FOR USE IN HUMANS. KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.**

Important Safety Information: The most common adverse events reported in decreasing order of reported frequency are: decreased appetite, depression/lethargy, shaking/shivering/tremor, vomiting, restlessness and anxiety, seizures, aggression, diarrhea, dilated pupils, vocalization, weight loss, panting, confusion, incoordination, and excessive salivation. Reconcile chewable tablets are not to be used in dogs with a history of seizures or when used with drugs that may cause seizures.

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.

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