

### FAQs for Veterinarians

### **Reconcile**

(fluoxetine hydrochloride)
Affordable, Reliable, Chewable.

#### Is Reconcile® a selective serotonin reuptake inhibitor?

Yes, the active ingredient in Reconcile chewable tablets is fluoxetine hydrochloride, a selective serotonin reuptake inhibitor (SSRI). When serotonin levels are low, communication between nerves may be impaired, producing increased anxiety. Reconcile helps correct the imbalance by blocking the reuptake of serotonin and temporarily increasing the level in the brain, which many experts believe improves communication between neurons and helps decrease anxiety.

### My patients are doing fine on generic fluoxetine and it is inexpensive. Why should I try to switch to Reconcile?

While off-label use of a human drug (e.g., generic fluoxetine) may have occurred in dogs, use of a formulation that has been clinically tested and FDA approved specifically for dogs is the better choice for several reasons.

- Reconcile is a once-daily, chewable, flavored tablet that is easier for pet owners to administer than generic fluoxetine capsules. Easier administration may lead to improved compliance.
- Reconcile tablets are available in four convenient strengths, 8 mg, 16 mg, 32 mg, and 64 mg, providing easy and accurate dosing for any size dog.
- The package insert attached to each bottle lists the correct dose for dogs, as well as possible side effects, based on clinical trials in dogs, not humans.
- Reconcile features the exclusive BOND™ behavior modification plan as well as clinic and pet owner educational materials and technical support for veterinarians.
- Reconcile now costs significantly less than when it was previously available, roughly one third the cost of the generic tablet, making it an affordable choice. (This cost distinction is not true of the generic capsule formulation.)
- Reconcile is offered by a trusted manufacturer in the veterinary community that provides veterinary technical support – by veterinarians, for veterinarians – which is not available for generic fluoxetine.

#### How long does it take to see an effect on behavior?

In a field study of Reconcile chewable tablets in client-owned dogs, 42% of dogs showed improvement within the first week. At the end of the 8-week study, 73% of dogs treated with Reconcile chewable tablets showed significant improvement (p=0.010).

### How can I set accurate expectations with clients to ensure optimal success?

Clients should keep in mind that their dog's individual response may vary due to a combination of factors. Advise your clients not to be discouraged if they don't see results within a week or two as a consistent outcome may take longer. It is important to stress that measurable results have occurred significantly faster when Reconcile is accompanied by the use of behavior modification training. Results of clinical trials have shown that after 8 weeks 73% of dogs receiving Reconcile and behavior modification training had significant behavioral improvement, compared with only 51% of dogs receiving behavior modification alone.<sup>1</sup>

# How can I educate clients to use Reconcile chewable tablets in concert with the BOND behavior training program?

It's important to emphasize the fact that the BOND behavior modification training is an essential component of treatment of canine separation anxiety with Reconcile. Client education materials are available for your use including a website specifically aimed at pet owners (Reconcile.com), which features a video illustrating how Reconcile works and outlines the BOND behavior training program, plus pet owner FAQs. In addition, your sales rep will provide you with a handout on the BOND behavior training program to be given to your clients in the clinic.

### Where can I send my client for more information?

Educational materials for pet owners are available at Reconcile. com.

### Can Reconcile be used in conjunction with seizure medications?

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).<sup>2</sup>

### Are there any contraindications for other medications for which Reconcile® should not be used?

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.<sup>2</sup>

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 coadministered with any drug that affects the cytochrome P450 enzyme system (for example, ketaconazole).<sup>2</sup>

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 four days following discontinuation.<sup>2</sup>

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.<sup>2</sup>

## Why is Reconcile not recommended for treatment of aggressive dogs?

Reconcile has not been studied or tested in aggressive dogs. Aggressive dogs can have varying degrees of unpredictable behavior and for that reason, it is not known how Reconcile will affect an aggressive dog if administered.

#### What is the washout period for this drug?

Because fluoxetine and its major metabolite, norfluoxetine, have long half-lives, a six-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.<sup>2</sup>

## If a patient is not doing well on Reconcile, can treatment be stopped immediately or is dose tapering recommended?

It is not necessary to taper or reduce doses when discontinuing treatment with Reconcile because of the long half-life of this product. Continued behavior modification is recommended to prevent recurrence of the clinical signs.

#### How frequently do I need to monitor blood work?

Professional judgment should be used in monitoring the patient for response to therapy and for adverse reactions. Reconcile caused no marked or consistent effects on hematology, blood chemistries or urinalysis in a one-year safety study in dogs.<sup>3</sup>

#### How do I report an adverse reaction?

Please call the manufacturer, PRN Pharmacal, at (850) 476-9462 to report an adverse event. Ask to speak to a technical services veterinarian, who will likely ask you a series of questions about the event, will complete an adverse drug experience reporting form, and will forward the report to the FDA's Center for Veterinary Medicine (CVM).

#### Can I prescribe Reconcile for longer than 8 weeks?

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.<sup>3</sup> Professional judgment, the individual veterinarian-client--pet relationship, and clinical status should be the criteria for monitoring the patient's response to therapy to determine the need to continue treatment with Reconcile chewable tablets beyond 8 weeks.

#### **REFERENCES**

- 1. Freedom of Information Summary NADA 141-272; Reconcile Fluoxetine Hydrochloride Chewable Tablets: Dogs. 2007:11.
- 2. PRN Pharmacal, Reconcile Product label, 2018.
- 3. Freedom of Information Summary NADA 141-272; Reconcile Fluoxetine Hydrochloride Chewable Tablets: Dogs. 2007:9.

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, 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, go to Reconcile.com.



As an employee-owned company, we have been dedicated to developing specialized therapeutics since 1978. Our commitment: quality solutions—as needed, when needed.

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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.