



CaniQuell™

Clomipramine HCl Tablets

What are Clomipramine Hydrochloride Tablets?

Clomipramine Hydrochloride Tablets belong to the dibenzazepine class of tricyclic antidepressants. Clomipramine Hydrochloride Tablets are to be used as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

What is separation anxiety?

Separation anxiety is a complex behavior disorder displayed when the owner (or other attachment figure) leaves the dog. The signs of separation anxiety evaluated in controlled trials were

- vocalization
- destructive behavior
- excessive salivation
- inappropriate elimination

In the absence of the owner or attachment figure, dogs with separation anxiety may exhibit one or more of these clinical signs. Although the owner (attachment figure) may inadvertently misinterpret this behavior, which only happens in their absence, as spiteful, it is thought to be the result of anxiety experienced by the dog.

Proper recognition of clinical signs, including a complete patient history and assessment of the patient's household environment, is essential to accurately diagnose and treat separation anxiety.

What can I expect when I give Clomipramine Hydrochloride Tablets?

Clomipramine Hydrochloride Tablets reduce the clinical signs of separation anxiety by affecting serotonergic and noradrenergic neuronal transmission in the central nervous system. While clomipramine hydrochloride can cause lethargy in dogs its mode of action is not as a sedative.

Inappropriate barking or destructive behavior, as well as inappropriate elimination (urination or defecation) may be alleviated by the use of Clomipramine Hydrochloride Tablets in conjunction with behavior modification.

How much should I give?

The recommended daily dose of Clomipramine Hydrochloride Tablets is 2 to 4 mg/kg/day (0.9-1.8 mg/lb/day).

It can be administered as a single daily dose or divided twice daily based on patient response and/or tolerance of the side effects. It -1.8 mg/lb/day). It can be administered as a single daily dose or divided twice daily based on patient response and/or tolerance of the side effects. It may be prudent to initiate treatment in divided doses to minimize side effects by permitting tolerance to side effects to develop or allowing the patient time to adapt if tolerance does not develop.

Once the desired clinical effect is achieved and the owners have successfully instituted the appropriate behavioral modification, the dose of Clomipramine Hydrochloride Tablets may be reduced to maintain the desired effect or discontinued. Withdrawal side effects were not reported in studies with Clomipramine Hydrochloride Tablets in dogs. However, in clinical practice, it is recommended to taper the individual patient dose while continuing to monitor the dog's behavior and clinical status through the dose reduction or withdrawal period. Continued behavioral modification is recommended to prevent recurrence of the clinical signs.

Can I administer with food?

To reduce the incidence of vomiting that may be experienced by some dogs, Clomipramine Hydrochloride Tablets may be given with a small amount of food.

When should I avoid using Clomipramine Hydrochloride Tablets?

Clomipramine Hydrochloride Tablets are contraindicated in dogs with known hypersensitivity to clomipramine or other tricyclic antidepressants. Clomipramine Hydrochloride Tablets should not be used in male breeding dogs. Testicular hypoplasia was seen in dogs treated for 1 year at 12.5 times the maximum daily dose.

Clomipramine Hydrochloride Tablets are contraindicated for use in dogs with a history of seizures or concomitantly with drugs which lower the seizure threshold.

Use with caution in dogs with cardiovascular disease. At 20 mg/kg/day (5X the maximum recommended dose), bradycardia and arrhythmias (atrioventricular node block and ventricular extrasystole) were observed in dogs. Because of its anticholinergic properties, clomipramine should be used with caution in patients with increased intraocular pressure, a history of narrow angle glaucoma, urinary retention or reduced gastrointestinal motility. Because clomipramine is principally metabolized in the liver, caution is advised in using this

medication in the presence of preexisting liver disease.

Prior to elective surgery with general anesthetics, clomipramine should be discontinued for as long as clinically feasible.

Can Clomipramine Hydrochloride Tablets be given with other medications?

Clomipramine Hydrochloride Tablets should not be given in combination, or within 14 days before or after treatment with a monoamine oxidase inhibitor [e.g. selegiline hydrochloride (L-deprenyl), amitraz].

Recommendations on the interaction between clomipramine and other medications are extrapolated from data generated in humans. Plasma levels of tricyclic antidepressants have been reported to be decreased by the concomitant administration of hepatic enzyme inducers (e.g., barbiturates, phenytoin); therefore plasma concentrations of clomipramine may be decreased by the concomitant administration of phenobarbital.

Plasma levels of closely related tricyclic antidepressants have been reported to be increased by the concomitant administration of hepatic enzyme inhibitors (e.g., cimetidine, fluoxetine). Tricyclic antidepressants themselves may exhibit hepatic enzyme inhibition and possibly increase plasma levels of barbiturates (phenobarbital). Caution is advised in using clomipramine with anticholinergic or sympathomimetic drugs or with other CNS-active drugs, including general anesthetics and neuroleptics.

What are the possible side effects of Clomipramine Hydrochloride Tablets?

Clomipramine Hydrochloride Tablets were demonstrated to be well-tolerated in dogs at the recommended label dose of 2-4 mg/kg/day. The most common side effects associated with Clomipramine Hydrochloride Tablets observed in a target animal safety study and post approval reporting were

- Emesis
- Lethargy
- Anorexia

It is important to stop the medication and contact your veterinarian immediately if you think your dog may have a medical problem or side effect while on Clomipramine Hydrochloride tablets.

If you have additional questions about possible side effects, talk with your veterinarian or call Mizner Bioscience, LLC at 1-561-570-1875.