

# **CLOMICALM**<sup>TM</sup>

(clomipramine hydrochloride)

## **Caution:**

Federal (USA) Law restricts this drug to use by or on the order of a licensed veterinarian.

## **Introduction:**

Elanco US, Inc. encourages you to take the time to read this package insert which describes the use of CLOMICALM Tablets for the treatment of separation anxiety in conjunction with behavior modification (training) in dogs. CLOMICALM Tablets do not act as a sedative. Instead, CLOMICALM Tablets help to reduce the anxiety associated with this condition, thus allowing your dog to more effectively benefit from behavior training. After reading this insert, if you have any questions about the use of CLOMICALM Tablets, please consult your veterinarian.

## **Description:**

CLOMICALM (clomipramine hydrochloride) Tablets belong to the dibenzazepine class of tricyclic antidepressants. Clomipramine hydrochloride is 3-chloro-5-[3-(dimethyl-amino)propyl]-10,11-dihydro-5H-dibenz[b,f]azepine monohydrochloride. CLOMICALM Tablets are oblong, light brown in color and contain clomipramine-hydrochloride formulated together with meat components.

## **Indications and Usage:**

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

Separation anxiety is a complex behavior disorder displayed when the owner (or other attachment figure) leaves the dog. In the absence of the owner or attachment figure, dogs with separation anxiety may exhibit one or more clinical signs. The signs of separation anxiety evaluated in controlled trials were vocalization, destructive behavior, excessive salivation, and inappropriate elimination. Although it may appear that this behavior, which only happens in the dog owner's absence, is a spiteful action, this behavior is thought to be a result of anxiety experienced by the dog. Therefore, punishment would not be appropriate for the dog with this behavior.

## **Behavior Modification (Training)**

Behavior training is a necessary component of therapy with CLOMICALM Tablets. In clinical trials, specific behavior training techniques were used at the following times:

- when the owner interacted with the dog while at home
- when the owner was preparing to leave the home
- when the owner returned home and greeted the dog

Since the methods used for behavior training can vary according to patient needs, it is important that you follow the instructions provided by your veterinarian regarding the specific techniques recommended for modifying your dog's behavior.

## **Contraindications:**

CLOMICALM Tablets are contraindicated in dogs with known hypersensitivity to clomipramine or related tricyclic antidepressants.

CLOMICALM 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.

CLOMICALM 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].

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

## **Human Warnings:**

**Not for use in humans. KEEP OUT OF REACH OF CHILDREN. In case of accidental ingestion seek medical attention immediately. In children, accidental ingestion should be regarded as serious. There is no specific antidote for clomipramine. Overdose in humans causes anticholinergic effects including effects on the central nervous (e.g., convulsions) and cardiovascular (e.g., arrhythmia, tachycardia) systems. People with known hypersensitivity to clomipramine should administer the product with caution.**

## **Precautions:**

It is important that your dog be closely monitored by your veterinarian while on a treatment plan with CLOMICALM Tablets and behavior training. You must inform your veterinarian of any current or future medications you are administering to your dog. The use of CLOMICALM Tablets in conjunction with certain other drugs or when your dog has other illnesses may be contraindicated or increase the risks of adverse reactions.

It is important that you inform your veterinarian of any changes in your dog's environment including, but not limited to, a new family member, a new pet, a move to a new location, or a change in your existing daily schedule. Some changes may result in an altered response to therapy.

It is important to inform your veterinarian of any perceived changes in your dog's behavior, appetite, or overall health while administering any medication. Some dogs display a temporary lethargy with the first few days of CLOMICALM treatment. In some cases, signs of separation anxiety, such as vocalization, may temporarily increase at the initiation of treatment. In an overdose situation, seek veterinary attention for your pet as soon as possible.

The safety and efficacy of CLOMICALM Tablets have not been established in dogs less than 6 months of age or in pregnant or lactating female dogs. CLOMICALM Tablets should not be used in breeding male dogs (see Contraindications). CLOMICALM Tablets are not recommended for other behavior problems, such as aggression.

## **Efficacy:**

CLOMICALM Tablets were tested in clinical trials involving client-owned dogs to determine effectiveness. CLOMICALM Tablets, at 2 – 4 mg/kg/day (0.9 – 1.8 mg/pound/day) when used in conjunction with behavior training accelerated both the time to improvement and the final result of separation anxiety therapy compared to behavioral training alone.

## **Adverse Reactions:**

The following adverse reactions have been reported associated with administration of CLOMICALM Tablets: lethargy/depression, vomiting, diarrhea, elevation in liver enzymes, convulsion(s), increased heart rate, decreased heart rate, increased thirst and confusion. Liver disease has occurred, especially in the presence of pre-existing conditions or with concurrent administration of drugs metabolized by the liver. In overdoses, signs such as vomiting, lethargy or depression, weakness and incoordination, dilated pupils, and vocalization may occur. Consult with your veterinarian if your dog experiences these or any other conditions.

In case of accidental human ingestion or accidental overdose in dogs, call 1-888-545-5973.

## **Dosage and Administration:**

The recommended daily dose of CLOMICALM Tablets is 2 to 4 mg/kg/day (0.9 – 1.8 mg/lb/day) (see dosing table below). Your veterinarian will instruct you to give the drug either once a day or divide the daily dose into 2 separate doses depending on your dog's response to the drug or tolerance to any side effects. CLOMICALM Tablets may be given with a small amount of food in an attempt to reduce the incidence of vomiting that may be experienced by some dogs. If a dose is missed, the next dose should be administered (without doubling) at the next scheduled dosing time.

Dog Weight (lbs.)	CLOMICALM per Day	No. Tablets per Day	Tablet Strength
2.75-5.5	5 mg	1	5 mg
5.6-10.9	10 mg	2	5 mg
11-22	20 mg	1	20 mg
22.1-44	40 mg	1	40 mg
44.1-88	80 mg	1	80 mg
88.1-176	160 mg	2	80 mg

Your veterinarian may decrease the dose or discontinue treatment with CLOMICALM Tablets depending on your dog's response to treatment. Continued behavior training is recommended, even after cessation of drug therapy.

## **Storage Conditions:**

Store in a dry place at controlled room temperature, between 59° and 77°F (15-25°C). Store unused tablets in the original closed container.

## **How Supplied:**

CLOMICALM Tablets are available in 5, 20, 40 and 80 mg tablet strengths in color-coded packaging for oral administration to dogs.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Manufactured for: Elanco US Inc., Greenfield, IN 46140, USA

NADA # 141 - 120, Approved by FDA

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