



## The SmartPak™ Pharmacy Dog & Cat Product Information Sheet

### Clomicalm® Tablets

**Common Drug Name** – Clomipramine

**How Supplied by SmartPak** – Clomicalm is available in 5, 20, 40 and 80mg tablet strengths in daily dose SmartPaks and in 30 count bottles.

**Category** – Clomicalm belongs to the dibenzazepine class of tricyclic antidepressants.

**Caution** - Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**Indications (Uses)** – Clomicalm is to be used as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

**Dosage and Administration** – The recommended daily dose of Clomicalm is 2 - 4mg/kg/day (0.9 - 1.8mg/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. To reduce the incidence of vomiting that may be experienced by some dogs, Clomicalm may be given with a small amount of food. Once the desired clinical effect is achieved and the owners have successfully instituted the appropriate behavioral modification, the dose of Clomicalm may be reduced to maintain the desired effect or discontinued. 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.

**Contraindications** – Clomicalm is contraindicated in dogs with known hypersensitivity to Clomipramine or other tricyclic antidepressants. Clomicalm 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 should not be given in combination, or within 14 days before or after treatment with a monoamine oxidase inhibitor (e.g. Selegiline, Amitraz). Clomicalm is contraindicated for use in dogs with a history of seizures or concomitantly with drugs which lower the seizure threshold.

**Human Warning** – Not for human use. 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.

**Warning** – For use in dogs only.

**Precautions** – Clomicalm is not recommended for other behavior problems, such as aggression. Studies to establish the safety and efficacy of Clomicalm in dogs less than 6 months of age have not been conducted. Periodic reassessment of hematological and serum biochemical data during the administration of this medication is advised. Use with caution in dogs with cardiovascular disease. 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 GI motility. Because Clomipramine is principally metabolized in the liver, caution is advised in using this medication in the presence of preexisting liver disease. Safety studies to determine the effects of Clomicalm in pregnant or lactating female dogs have not been conducted. The effectiveness and clinical safety of Clomicalm for long-term use (i.e., for more than 12 weeks) has not been evaluated.

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**Drug Interactions** – Recommendations on the interaction between Clomipramine and other medications are extrapolated from data generated in humans. Plasma concentrations of Clomipramine have been reported to be increased 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). Plasma levels of closely related tricyclic antidepressants have been reported to be decreased by the concomitant administration of hepatic enzyme inducers (e.g. barbiturates, Phenytoin). Caution is advised in using Clomipramine with anticholinergic or sympathomimetic drugs or with other CNS-active drugs, including general anesthetics and neuroleptics. Prior to elective surgery with general anesthetics, Clomipramine should be discontinued for as long as clinically feasible.

**Adverse Reactions (Side Effects)** – The most common adverse reactions observed in dogs dosed with Clomicalm or placebo were vomiting and lethargy.

**Storage Conditions:** Store in a dry place at controlled room temperatures between 59 – 86F. Store unused tablets in the original closed container.

**Manufactured for:**  
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