

Product Name: CLOMICALM 80 TABLETS FOR DOGS
APVMA Approval No: 50185/123131



Label Name:	CLOMICALM 80 TABLETS FOR DOGS
Signal Headings:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
Constituent Statements:	80 mg/Tb CLOMIPRAMINE HYDROCHLORIDE (equivalent to 72 mg clomipramine)
Claims:	For the treatment of stereotypic behaviours (obsessive-compulsive disorders) and as an aid in the treatment of anxiety disorders, in dogs weighing between 20 and 80 kg.
Net Contents:	30 divisible flavoured tablets
Directions for Use:	
Restraints:	
Contraindications:	
Precautions:	<p>Precautions: Special precautions for use: From its known mechanism of action, it is recommended to use CLOMICALM with care in dogs or cats with cardiac arrhythmias, epilepsy or narrow angle glaucoma. CLOMICALM should be used with caution in dogs and cats with a known predisposition to developing urinary tract obstruction or urinary retention. CLOMICALM is not recommended for treatment of aggression, or for treating a dog or cat for the above indicated behaviours where that animal has a history or predisposition to aggressive behaviour.</p> <p>The efficacy and safety of CLOMICALM has not been established in dogs and cats weighing less than 1.25 kg or less than six months of age.</p> <p>Clomipramine hydrochloride is metabolised by hepatic glucuronidation – as cats use this pathway less efficiently than dogs, special care must be taken when prescribing CLOMICALM 5 in cats.</p>

	<p>Use during pregnancy and lactation: The safety of CLOMICALM has not been established in breeding or lactating dogs or cats. CLOMICALM is recommended for use in breeding dogs and cats only if the benefit/risk ratio is considered justified by the veterinarian.</p> <p>Interactions with other medications: The need for specific precautions has not been established in dogs or cats. In clinical trials, there were no adverse effects when CLOMICALM was used with a variety of antibiotics, vaccines, anti-parasitic drugs, and CNS active drugs. CLOMICALM may potentiate the effect of CNS depressant drugs (e.g. barbiturates). CLOMICALM may also potentiate the effects of catecholamines (e.g. adrenaline) anticholinergic drugs and second-generation diazepines (not diazepam). It is recommended not to administer CLOMICALM in combination with, or within 2 weeks of cessation of therapy with, monoamine oxidase inhibitors.</p> <p>Overdose: Oral administration of clomipramine at 40 mg/kg (10–20 times the recommended dose rate) caused only mild, transient signs of toxicity in dogs. Prolonged administration of doses \geq 40 mg/kg should be avoided. Administration of toxic doses of clomipramine (735 mg/kg) to dogs caused non-specific signs of CNS inhibition and convulsions. There is no specific antidote. In the event of overdose, treatment should be supportive.</p>
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Side Effects:	<p>When used as directed, CLOMICALM may cause mild, transient side effects e.g. sedation, anorexia, or increased vomiting. The latter may be reduced by giving the medication with food. In very rare instances, CLOMICALM may cause urinary retention in cats due to the potential for anticholinergic effects.</p>
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Dosage and Administration:	<p>If dispensing tablets, this must be done into another child-resistant container.</p> <p>Dogs: CLOMICALM should be administered twice daily at a dose rate of 1–2 mg clomipramine hydrochloride/kg body weight to give a total daily dose of 2–4 mg/kg according to the table below. Cats: CLOMICALM should be administered once daily at a dose rate of 0.3–1.0 mg clomipramine hydrochloride/kg body weight according to the table below.</p> <p>CLOMICALM is given orally, preferably with food.</p> <p>Dogs: In clinical trials, CLOMICALM administered for 2–3 months in combination with appropriate behaviour modification techniques has been shown to favourably enhance and accelerate the response to behaviour modification in the treatment of anxiety disorders in dogs (generalised anxiety and anxiety when separated from the owner). CLOMICALM has been shown to also be effective in the treatment of stereotypic behaviours (obsessive-compulsive disorder) in dogs such as acral lick dermatitis when administered for a minimum of 1 month. Cats: CLOMICALM, in combination with behavioural modification, is effective as an aid in the treatment of urine spraying in desexed and female cats. If the cat appears sedated, the lower end of the dose range can be used.</p> <p>Tailing Off It may be advisable to “tail off” or gradually reduce the dose of clomipramine at the end of a course of treatment.</p> <p>This section contains file attachment.</p>
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General Directions:	<p>Indications Treatment of stereotypic behaviours (obsessive-compulsive disorders) in dogs such as acral lick dermatitis, excessive grooming and tail chasing. An aid in the treatment of anxiety disorders in dogs such as destructiveness, excessive vocalisation, loss of toilet control, associated with separation anxiety. An aid in the treatment of urine spraying in desexed and female cats.</p> <p>Pharmacological properties CLOMICALM contains clomipramine hydrochloride. In vivo, both clomipramine and its major metabolite, desmethylclomipramine are active. Both clomipramine and desmethylclomipramine contribute to the broad spectrum action of CLOMICALM by blocking the neuronal reuptake of both noradrenaline and serotonin (5-HT). CLOMICALM, therefore, combines the properties of both a tricyclic anti-depressant and a serotonin reuptake inhibitor.</p>
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Withholding Periods:	
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Trade Advice:	
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Safety Directions:	
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First Aid Instructions:	<p>If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26; New Zealand 0800 764 766.</p>
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First Aid Warnings:	
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Additional User Safety:	<p>In children, accidental ingestion should be regarded as serious. There is no specific antidote. In case of accidental ingestion, seek medical advice immediately and show the product label.</p>
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Environmental Statements:	
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Disposal:	Dispose of empty container by wrapping with paper and putting in the garbage.
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Storage:	Store below 30 °C (room temperature). Store in a dry place. Store unused product in the original closed container.
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Dosage and administration:

Dogs: CLOMICALM should be administered twice daily at a dose rate of 1–2 mg clomipramine hydrochloride/kg body weight to give a total daily dose of 2–4 mg/kg according to the table below.

Cats: CLOMICALM should be administered once daily at a dose rate of 0.3–1.0 mg clomipramine hydrochloride/kg body weight according to the table below.

	Body weight	Dosage per administration*		
		CLOMICALM 5	CLOMICALM 20	CLOMICALM 80
Dogs	1.25–2.5 kg	0.5 tablet		
	>2.5–5 kg	1 tablet		
	>5–10 kg		0.5 tablet	
	>10–20 kg		1 tablet	
	>20–40 kg			0.5 tablet
	>40–80 kg			1 tablet
Cats	3–6 kg	0.5 tablet		
	>6–12 kg	1 tablet		

*twice daily for dogs; once daily for cats

CLOMICALM is given orally, preferably with food.

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CLOMICALM 80			50185