

Previcox Chewable Tablets

Introduction



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Presentation

Tan-brown, round, convex, engraved, scored chewable tablets, each containing 57mg or 227 mg firocoxib.

Uses

Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the Coxib group, which acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. PREVICOX tablets are for the relief of pain and inflammation associated with osteoarthritis in dogs and for the relief of post-operative pain and inflammation associated with soft-tissue surgery in dogs.

Dosage and administration

Osteoarthritis:

The recommended oral dose is 5 mg per kg bodyweight once daily, as shown in the table below. Tablets can be administered with or without food. Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, this should be borne in mind when considering longer-term treatment, with regular monitoring carried out by the veterinarian.

Relief of post-operative pain:

The recommended oral dose is 5 mg per kg bodyweight once daily, as shown in the table below, for up to 3 days as needed, starting approximately 2 hours prior to surgery.

Body weight (kg)	Number of chewable tablets		mg/kg range
	57mg	227mg	
3 - 5.5	0.5		5.2 - 9.5
5.6 - 10	1		5.7 - 10.2
10.1 - 15	1.5		5.7 - 8.5
15.1 - 22		0.5	5.2 - 7.5
22.1 - 45		1	5.0 - 10.3
45.1 - 68		1.5	5.0 - 7.5
68.1 - 90		2	5.0 - 6.7

Contra-indications, warnings, etc

For animal treatment only. Do not exceed the recommended dose. Do not use in pregnant or lactating bitches.

Do not use in animals less than 10 weeks of age or less than 3 kg body weight. Do not use in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders. Where there is a risk of gastrointestinal bleeding, or if the animal previously displayed intolerance to NSAIDs, use this product under strict veterinary monitoring.

Vomiting and diarrhoea have occasionally been reported. These reactions are generally of a transitory nature and are reversible when the treatment is stopped.

Do not use concomitantly with corticosteroids or other NSAIDs. Use in very young animals, or animals with suspected or confirmed impairment of renal, cardiac or hepatic function may involve additional risk. If such use cannot be avoided, those dogs require careful veterinary monitoring.

Avoid use in any dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

The treatment should be discontinued and the advice of a veterinarian should be sought if any of these signs are observed: repeated diarrhoea, vomiting, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters.

Laboratory studies in rabbits have shown evidence of maternotoxic and foetotoxic effects at dose rates approximating the recommended treatment dose for the dog. Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment with PREVICOX. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

PREVICOX must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.

Concomitant treatment with molecules displaying action on renal flow, e.g. diuretics or Angiotensin Converting Enzyme (ACE) inhibitors, should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic drugs should be avoided, as there might be an increased risk of renal toxicity. As anaesthetic drugs may affect renal perfusion, the use of parenteral fluid therapy during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

Concurrent use of other active substances that have a high degree of protein binding may compete with firocoxib for binding and thus lead to toxic effects.

In the event of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician. Wash hands after use of the product.

Return halved tablets to the blister and keep out of the reach of children.

Disposal advice

Any unused product or waste material should be disposed of in accordance with local requirements.

Pharmaceutical precautions

Do not store above 30°C. Store in the original package. Halved tablets may be kept for up to 7 days in the original container.

Legal category

POM-V

Packaging Quantities

PREVICOX tablets are supplied in carton boxes containing blisters (transparent PVC /aluminium foil and paper backing).

The chewable tablets are available in the following pack sizes:

57mg: 1 carton box containing three blisters of 10 tablets

227 mg: 1 carton box containing one blister of 10 tablets

1 carton box containing three blisters of 10 tablets

Further information

Firocoxib is approximately 96% bound to plasma proteins. Following multiple oral administrations, the steady state is reached by the third daily dose.

Firocoxib is metabolised predominantly by dealkylation and glucuronidation in the liver. Elimination is principally in the bile and gastrointestinal tract.

PREVICOX chewable tablets are scored to facilitate accurate dosing and contain caramel and smoke flavours to facilitate administration to dogs.

Mode of action: Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) that acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. COX-2 is the isoform of the enzyme that has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. In in-vitro canine whole blood assays, firocoxib exhibited approximately 380-fold selectivity for COX-2 over COX-1.

Significant Changes

Previcox	Merial	Addition	20/06/2008
Chewable	Animal	claim	
Tablets	Health	for	
	Ltd	relief of	
		post-	
		operative	
		pain	
		and	
		inflammation	
		associated	
		with	
		soft-	
		tissue	
		surgery	
		in dogs.	
ProteqF	Merial	New	11/06/2008
	Animal	influenza	
	Health	strain	
	Ltd	(Ohio/3).	

Marketing authorisation number

EU/2/04/045/001-4.