TOFAMATE TAB 60

MacroPhar

Brand or Product Name :

TOFAMATE TAB 60

Name and Strength of Active Substance(s)

Each Tablet Contains : Tolfenamic Acid 60 mg

Product Description : White, round, biconvex tablets with score line on one side.

Pharmacodynamics :

Tolfenamic acid (N-(2-methyl-3-chlorophenyl) anthranilic acid) is a non-steroidal anti-inflammatory drug belonging to the fenamate group. Tolfenamic acid possesses anti-inflammatory, analgesic and antipyretic properties.

The anti-inflammatory activity of tolfenamic acid is due to inhibition of cyclooxygenase leading to a reduction in prostaglandin and thromboxane synthesis, major inflammatory mediators.

Pharmacokinetics :

Absorbtion :

In the dog, tolfenamic acid is rapidly absorbed. After a single oral administration of 4 mg/kg tolfenamic acid, the mean maximal plasma concentration (Cmax) of about 4 µg/ml is reached in about 1 hour. When the same intake of tolfenamic acid is taken with food, Cmax is 1.9 ± 1.4 µg/ml. These variations are due to a strong enterohepatic recycling of the product.

Distribution, metabolism, excretion :

Tolfenamic acid is distributed in all organs with a strong concentration in plasma, digestive tract, liver, lungs and kidneys. The concentration in the brain however is low.

Tolfenamic acid and its metabolites do not cross the placenta barrier to any great extent.

Tolfenamic acid is excreted mainly unchanged.

In dogs with renal insufficiency, the elimination of tolfenamic acid is unchanged.

Indication :

In Dogs : Treatment for alleviation of acute episodes of inflammation and pain in chronic locomotor disease.

Recommended Dosage :

4 mg tolfenamic acid/kg once daily, i.e. 1 tablet of TOFAMATE TAB 60 for 15 kg of bodyweight once daily, administered in feed for continually 3 days. Please see the table below for the dosage by weight of the animal.

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Weight of the animal (kg)	Number of tablets
7 - 10	1/2
10 - 20	1
20 - 25	1 1/2
25 - 35	2
35 - 40	2 1/2
> 45	3

Subject to clinical response, the administration may be repeated every 7 days, i.e. 3 days for medication followed by 4 days without medication.

Mode of Administration : Oral route.

Contraindications :

- Do not administer to animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia or hypersensitivity to the product.

Warnings and Precautions :

Precautions for use in animals

- Not for use in dogs under 7 kg bodyweight.
- Use in animal less than 6 weeks of age, or in aged animals, may involve additional risk. If such a use cannot be avoided, animals may require a reduced dosage and careful clinical management.
- Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

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- Concurrent administration of potential nephrotoxic drugs should be avoided.
- It is preferable that the product is not administered to animals undergoing general anaesthesia until fully recovered.
- Do not exceed the prescribed dosage or duration of treatment.
- Animals suffering from a chronic renal insufficiency and requiring an anti-inflammatory treatment may be treated with tolfenamic acid without requiring an adjustment of the dosage. However, the use of this product is contraindicated in acute case of renal insufficiency.
- In case of undesirable effects (anorexia, vomiting, diarrhea, presence of blood in feces) occurring during the treatment, your veterinarian should be contacted for advice.
- Long term treatment of over 3 months duration should be under regular veterinary supervision. In particular, dogs with hepatic insufficiency should be closely monitored.

Precautions for the person administering the veterinary medical product to animals

- In case of accidental contact with eyes, wash with plenty of water.

Special warnings for each target species :

- NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections appropriate concurrent antimicrobial therapy should be instigated.

Interactions with Other Medicaments :

Do not administer NSAIDs concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs, which can lead to toxic effects.

Statement on usage during pregnancy and lactation :

Although studies in laboratory animals did not show any effect on reproduction, it is not advisable to administer the product during gestation.

Adverse Effects/ Undesirable Effects :

Diarrhoea and vomiting may occur in rare cases during the treatment. Moreover, a temporary increase of thirst and/or dieresis may occur. In most of the cases, these signs cease spontaneously after the treatment.

Overdose and Treatment :

In case of overdose, administer symptomatic treatment.

Withdrawal Period(s) :

Not applicable.

Storage Conditions :

Keep in tight containers. Protect from light. Store below 30°C.

Keep out of reach of children/ Jauhi daripada kanak-kanak

Dosage Forms and packaging available :

10 tablets are filled in a clear, amber PVC-ALU blister and then 1, 2, 4, 5, 10, 50, 100 blisters are packed in carton.

Not all pack sizes may be marketed.

Date of Revision of Package Insert : 18/09/2023

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Name and Address of Manufacturer and Product Registration Holder :

Manufactured by : MacroPhar Co., Ltd.

89 Soi Pattanakarn 20 Yaek 4, Pattanakarn Road, Suan Luang, Bangkok 10250 Thailand.
Tel : (662)314-6671 Fax : (662)318-6091

Product Registration Holder : Stadpharm Sdn. Bhd.

E-9-01, Oasis Square, Ara Damansara, No. 2, Jalan PJU 1A/7A, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.