



TOLXEL 6MG PALATABLE TABLETS

Description and Composition

TOLXEL 6MG PALATABLE TABLETS is a white tablet, with score. Each tablet contains 6mg Tolfenamic Acid as its active ingredient.

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

Absorption:

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

In the cat, the absorption is very fast. After a single oral administration of 4mg / kg tolfenamic acid, the mean maximal plasma concentration (Cmax) of about 5.6µg / ml is reached in about 1 hour.

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

Small dogs: Treatment for the alleviation of acute episodes of inflammation and pain in chronic locomotor disease.

Cats: In febrile syndrome (abscess, fever of unknown origin).

Recommended Dose

Oral administration with food.

4mg tolfenamic acid / kg once daily, i.e. 1 tablet for 1.5kg of body weight administered in feed for 3 days according to the following:

1kg – 2kg: 1 tablet
2.5kg – 3.5kg: 2 tablets
3.5kg – 4.5kg: 3 tablets

In dogs, subject to clinical response, the administration may be repeated every 7 days, i.e. 3 days of medication followed by 4 days without medication.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Route of Administration

To be given by oral administration in cats and dogs.

Contraindication

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.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Warning and Precautions

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.

In dogs, long term treatment of over 3 months duration should be under regular veterinary supervision. In particular, dogs with hepatic insufficiency should be closely monitored.

Special precautions for use

Special precautions for use in animals

Use in animals 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.

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 cases of renal insufficiency.

In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during the treatment, your veterinarian should be contacted for advice.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

Interaction 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.

Pregnancy and Lactation

The use is not recommended during pregnancy.

Laboratory studies in animals have not produced any evidence of effects on reproduction.

Side Effects

Dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting ¹ , diarrhoea ¹ Polyuria ^{1,2} Polydipsia ^{1,2}
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¹ In most of the cases, these signs cease spontaneously after the treatment

² Temporary

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

Symptoms and Treatment of Overdose

In case of overdose, administer symptomatic treatment.

Storage Condition

Store below 30°C. Protect from light.

Shelf life

3 years.

Packing

30, 60, 100, 120, 200, 500 tablets

Manufacturer & Product Registration Holder

Range Pharma Sdn Bhd

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