VET'S CARE LINE

TOLXEL 60MG PALATABLE TABLETS

Description and Composition
TOLXEL 60MG PALATABLE TABLETS is a white tablet, with score. Each tablet contains 60mg 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:
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 ± 1.4µg / 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
Dogs: Treatment for the alleviation of acute episodes of inflammation and pain in chronic locomotor disease.

Recommended Dose
Oral administration with food.
4mg tolfenamic acid / kg once daily, i.e. 1 tablet for 15kg of body weight administered in feed for 3 days according to the following:

7kg – 10kg: ½ tablet
10kg – 20kg: 1 tablet
20kg – 25kg: 1 ½ tablets
25kg – 35kg: 2 tablets
35kg – 40kg: 2 ½ tablets
> 45kg: 3 tablets

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 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.

See also Special precautions for use.

Special precautions for use
Special precautions for use in animals
Not for use in dogs under 7kg body weight.

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 tablets are 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.

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

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:

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting[1], diarrhoea[1] Polyuria[1,2] Polydipsia[1,2]

[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 30ºC. 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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