SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine Tablets 60mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Tolfenamic acid 60mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
White convex tablets, divisible in two.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

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.

4.4 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 4.5

4.5 Special precautions for use

(i) Special precautions for use in animals

Not for use in dogs under 7 kg bodyweight.

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 Tolfedine 60mg 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 contra-indicated 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 of over 3 months duration should be under regular veterinary supervision. In particular, dogs with hepatic insufficiency should be closely monitored.

(ii) 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.
For animal treatment only

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

4mg tolfenamic acid/kg once daily, i.e. 1 tablet for 15kg of bodyweight administered in feed for 3 days according to the following table:

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, ie 3 days of medication followed by 4 days without medication.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose, administer symptomatic treatment.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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.

Pharmacokinetic properties:

<u>Absorption</u> :

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate Dihydrate
Wheat Starch
Docusate Sodium
Microcrystalline Cellulose
Magnesium Stearate

6.2 Incompatibilities

None known

6.3 Shelf life

The shelf life of the veterinary medicinal product as packages for sale 3 years.

6.4. Special precautions for storage

Do not store above 25^{o}C. Store in a dry place

6.5 Nature and composition of immediate packaging

Box of 1 PVC-aluminium blisters of 8 tablets
Box of 2 PCV-aluminium blisters of 8 tablets
Box of 12 PVC-aluminium blisters of 8 tablets
Box of 24 PVC-aluminium blisters of 8 tablets
Box of 48 PVC-aluminium blisters of 8 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

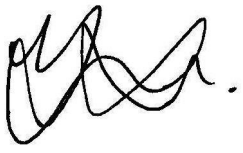
Vm 08007/4050

9. DATE OF FIRST AUTHORISATION

15 October 2023

10. DATE OF REVISION OF THE TEXT

October 2023



Approved: 13 October 2023