Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 6 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tablet contains:

Active Substance:
Tolfenamic Acid 6 mg
For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, Cats

4.2 Indications for use, specifying the target species

Cat: Febrile syndromes (abscess, fever of unknown origin)Dog: Acute flare ups of chronic locomotor disease

4.3 Contraindications

Concurrent administration with other steroidal or non-steroidal anti-inflammatory drugs.
Do not use in animals with suspected gastro-duodenal ulceration.
Do not use in animals with impaired renal or hepatic function.Do not use in pregnant animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Do not exceed the stated dose or duration of treatment.

Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided, careful clinical management is essential. Reduced metabolism and excretion in these animals should be considered.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal as there is a potential risk of increased renal toxicity.
It is preferable that TOLFEDINE is not administered to animals undergoing general anaesthesia until fully recovered.
Where there is appearance of bloody or black faeces, a veterinary surgeon should be contacted for advice and the possibility of stopping treatment should be considered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

Diarrhoea and vomiting may occur during treatment. Where either persists, treatment should be discontinued.

4.7 Use during pregnancy, lactation or lay

Do not treat pregnant animals.

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer concomitantly with a non steroidal anti-inflammatory or within 24 hours. Tolfenamic acid is strongly bound to plasma proteins and may come into competition with other substances strongly bound.

4.9 Amounts to be administered and administration route

The recommended dosage rate is 4 mg tolfenamic acid per kg bodyweight once daily for 3 to 5 days. Administration is by oral route with food.

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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory and antirheumatic products, Fenamates
ATCvet Code: QM01AG02

5.1 Pharmacodynamic properties

Tolfenamic acid (N-52-methyl-3-chloropentyl anthranilic acid) belongs to the fenamate group. Substances of this group exert anti-inflammatory, analgesic and antipyretic activities and are classified as non steroidal anti-inflammatory drugs (NSAID). The anti-inflammatory activity of tolfenamic acid is mainly due to an inhibition of cyclo-oxygenase and thus a reduction of the synthesis of prostaglandins which are important inflammatory mediators.

5.2 Pharmacokinetic particulars

The pharmacokinetics of tolfenamic acid have been investigated in laboratory animals, in man and in the target species, dogs and cats.

Absorption

In the dog, tolfenamic acid is readily absorbed either by oral or by injectable administration. By the oral route, a Cmax of about 4 µg/ml is attained about 1 hour after a single dose of 4 mg/kg. When administered at the same dose with a meal, the Cmax is 2 ± 3 µg/ml. This variation can be accounted for by greater enterohepatic recycling when administered with food. By injection, maximum plasma concentrations of about 4 µg /ml (s.c) and about 3 µg/ml (i.m.) are obtained 2 hours after administration at 4 mg/kg.

In cats, absorption is quite rapid. By the oral route, after a dose of 4 mg/kg, a mean maximum plasma concentration of about 5.6 µg/ml is attained. The mean Tmax is observed after 1 hour. By injection, a peak of 3.9 µg/ml is obtained within 1 hour of administration at 4 mg/kg.

Distribution

In the dog and cat, over 99% of tolfenamic acid is bound to plasma proteins.

Biotransformation

The metabolic fate of tolfenamic acid has been studied in the rat, rabbit, dog and in man. The extent of metabolism depends on the species concerned. In the rat, man and the rabbit , the main metabolites are two hydroxy-metabolites. On the contrary, in the dog, there is no formation of hydroxy-metabolites, only tolfenamic acid and its conjugate with glucuronic acid are found in urine.

Elimination
The hydroxylated metabolites and their conjugates are mainly excreted by the kidneys. The unchanged tolfenamic acid and its glucuronides are predominantly excreted into the bile. Moreover, tolfenamic acid undergoes an intensive enterohepatic recycling.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wheat Starch
Calcium Hydrogen Phosphate
Docusate Sodium
Microcrystalline Cellulose
Magnesium Stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

The veterinary medicinal prodcut does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Tablet description: white circular biconvex uncoated tablet.

Box of 1 PVC-aluminium blisters of 8 tablets.
Box of 2 PVC-aluminium blisters of 8 tablets.
Box of 2 PVC-aluminium blisters of 10 tablets.
Box of 10 PVC-aluminium blisters of 10 tablets.
Box of 20 PVC-aluminium blisters of 10 tablets.

Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
First Floor
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19/20 Earlsfort Terrace
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10983/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th August 1993
Date of last renewal: 11th August 2008

10 DATE OF REVISION OF THE TEXT

August 2015