1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 60 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Tolfenamic acid 60 mg

Excipients:

Qualitative composition of excipients and other constituents
Wheat Starch
Calcium Hydrogen Phosphate
Docusate Sodium
Microcrystalline Cellulose
Magnesium Stearate

White circular biconvex uncoated tablet, divisible in two.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of acute inflammation due to chronic locomotor disease.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 the veterinary medical product 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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1]

[1] Where either persists, treatment should be discontinued.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

Oral use with food.

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

The recommended dosage rate is 4 mg tolfenamic acid per kg bodyweight once daily for 3 to 5 days.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, administer a symptomatic treatment.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AG02.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Box of 1 PVC-aluminium blister of 8 tablets.
Box of 2 PVC-aluminium blisters of 8 tablets.
Box of 12 PVC-aluminium blisters of 8 tablets.
Box of 1 PVC-aluminium blisters of 10 tablets.
Box of 2 PVC-aluminium blisters of 10 tablets.
Box of 10 PVC-aluminium blisters of 10 tablets.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10983/018/002

8. DATE OF FIRST AUTHORISATION

12/08/1993

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

01/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).