SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 6 mg Tablets for Cats and Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Tolfenamic acid 6 mg

Excipients:

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

White convex tablets.

3. CLINICAL INFORMATION

3.1 Target species

Cats and Dogs.

3.2 Indications for use for each target species

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

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

3.3 Contraindications

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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

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. 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:

The use is not recommended during pregnancy.

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

3.8 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.

3.9 Administration routes and dosage

Oral administration with food.

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

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

Weight of the animal (kg)	Number of tablets
1 - 2	1
2.5 - 3.5	2
3.5 - 4.5	3

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

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

In case of overdose, administer 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-(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.

4.3 Pharmacokinetics

Absorption:

In the dog, tolfenamic acid is rapidly absorbed. After a single oral administration of 4 mg/kg tolfenamic acid, the mean maximal plasma concentration (Cmax) of about 4 µg/ml is reached in about 1 hour. When the same intake of tolfenamic acid is taken with food, Cmax is 1.9 ± 1. 4 µg/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 4 mg/kg tolfenamic acid, the mean maximal plasma concentration (Cmax) of about 5.6 µg/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.

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

Do not store above 25°C.

Store in a dry place.

5.4 Nature and composition of immediate packaging

Box of 1 PVC-aluminium blister of 10 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.

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

Medicines should not be disposed of via wastewater.

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 UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/4049

8. DATE OF FIRST AUTHORISATION

15 October 1993

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

July 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 08 December 2025

Gavin Hall