1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 40 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Tolfenamic acid 40 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	10.4 mg
Ethyl digol	
Ethanolamine	
Water for injection	

A clear colourless to slightly yellow sterile aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

In dogs: inflammatory and painful post-operative syndromes.
In cats: adjuvant treatment of upper respiratory disease in association with antimicrobial therapy.

3.3 Contraindications

Do not use in cases of cardiac disease.
Do not use in cases of impaired hepatic function or acute renal insufficiency.
Do not use in cases of ulceration or digestive bleeding.
Do not use in cases of blood dyscrasia.
Do not use in cases of hypersensitivity to the active substance.
Do not inject intramuscularly in cats.

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.

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 is essential. Reduced metabolism and excretion in these animals should be considered.

Avoid use in any dehydrated, hypovolemic 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 veterinary medicinal product is not administered to cats undergoing general anaesthesia until fully recovered.

Do not exceed the prescribed dosage or duration of treatment. The scale of pain relief after pre-operative administration may be influenced by the severity and duration of the operation.

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 veterinary medicinal 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 and the possibility of stopping treatment should be considered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of eye or skin contact, wash immediately with water.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1] Polyuria[2] Polydipsia[2] Injection site reaction

[1] Where either persists treatment should be discontinued
[2] Temporary. In most cases, these signs disappear spontaneously when treatment is stopped

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 its local representative 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 other 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

Dogs: Intramuscular (**i.m.**) or subcutaneous (**s.c.**) use.
Cats: Subcutaneous use.

The recommended dose is 4 mg/kg bodyweight. That is a single injection of 1 ml/10 kg, repeated once after 24 hours if required (1 ml/10 kg) or a single injection of 1 ml/10 kg, the treatment being continued by the oral route, using tablets.

In dogs: administer by intramuscular or subcutaneous injection. For the treatment of post-operative pain, this is best given pre-operatively, either at the time of pre-medication or induction of anaesthesia.

In cats: administer by the subcutaneous route only.

The use of insulin-type needle/syringe is advisable particularly in low-weight animals to ensure an accurate dose.

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-(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

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

Absorption:
In dogs, tolfenamic acid is readily absorbed by injectable administration. 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 injection, a peak of 3.9 µg/ml is obtained within 1 hour of administration at 4 mg/kg.

Distribution, metabolism, excretion:
In dogs and cats, over 99% of tolfenamic acid is bound to plasma proteins.
The metabolic fate of tolfenamic acid has been studied in rats, rabbits, dogs and in man. The extent of metabolism depends on the species concerned. In rats, man and rabbits, the main metabolites are two hydroxy-metabolites. On the contrary, in dogs, there is no formation of hydroxy-metabolites, only tolfenamic acid and its conjugate with glucuronic acid are found in urine.

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.

Tolfenamic acid is distributed to all organs with high concentrations 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 placental barrier to any great extent.

In dogs with renal insufficiency, the elimination of tolfenamic acid is unchanged and accumulation does not occur.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

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

Cardboard box with 1 amber Type I glass vial of 10 ml, with a chlorobutyl rubber bung with aluminium overseal with or without flip top cap.

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 S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/038/001

8. DATE OF FIRST AUTHORISATION

12/08/1993

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

11/09/2026

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).