PARTICULARS TO APPEAR ON THE OUTER PACKAGE: OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 6 mg Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Active substance:

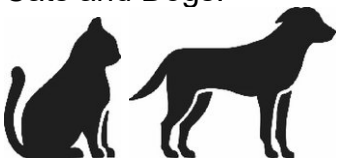
Tolfenamic acid 6 mg

3. PACKAGE SIZE

10 tablets.
20 tablets.
100 tablets.
200 tablets.

4. TARGET SPECIES

Cats and Dogs.



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral administration.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C

Store in a dry place.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 08007/4049

15. BATCH NUMBER

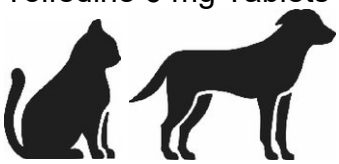
Lot {number}

Vetoquinol logo

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS: BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 6 mg Tablets



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains:

Active substance:

Tolfenamic acid 6 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Tolfedine 6 mg Tablets for Cats and Dogs
Tolfedine 20 mg Tablets for Dogs
Tolfedine 60 mg Tablets for Dogs

2. Composition

Each tablet contains:

Tablet	Active Substance	
Tolfedine 6 mg Tablets for Cats and Dogs	Tolfenamic acid	6 mg
Tolfedine 20 mg Tablets for Dogs	Tolfenamic acid	20 mg
Tolfedine 60 mg Tablets for Dogs	Tolfenamic acid	60 mg

White convex tablets.
Tolfedine 20mg tablets and Tolfedine 60mg tablets are divisible in two.

3. Target species

Cats and Dogs.

4. Indications for use

Cats - In febrile syndrome (abscess, fever of unknown origin).

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

5. Contraindications

Do not administer to animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding or 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.

6. Special warnings

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.

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.

Pregnancy:

The use is not recommended during pregnancy.

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

Interaction with other medicinal products and other forms of interaction:

Do not exceed the prescribed dosage or duration of treatment and 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. Do not administer in conjunction with glucocorticosteroids.

Overdose:

In case of overdose, administer symptomatic treatment.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral administration with food.

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

The recommended dosage is 4 mg tolfenamic acid/kg bodyweight by oral administration with food once daily for 3 days according to the following table:

Bodyweight (kg)													
	1-2	2.5-3.5	3.5-4.5	4-6	6-8	8-10	10-12.5	12.5-15	7-10	10-20	20-25	23-35	35-40	>45
Number of 6 mg Tablets	1	2	3											
Number of 20 mg tablets				1	1.5	2	2.5	3						
Number of 60 mg tablets									0.5	1	1.5	2	2.5	3

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

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton or the blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 08007/4049

Box of 1 blister of 10 tablets.
Box of 2 blisters of 10 tablets.
Box of 10 blisters of 10 tablets.
Box of 20 blisters of 10 tablets.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Vetoquinol UK Limited
Pury Hill Business Park
Steadings Barn
Towcester NN12 7LS
United Kingdom
Tel: +44 1280 814 500

Manufacturer responsible for batch release:

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

17. Other information

POM-V

This product may be used to continue treatment begun with Tolfedine 4% Injection.

Vetoquinol logo

Approved 08 December 2025

Gavin Hall