

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 4% Solution for Injection for Use in Dogs and Cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains tolfenamic acid 40mg as active ingredient with benzyl alcohol 10.4mg and sodium formaldehyde sulfoxylate dihydrate 5mg as preservatives

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10, 20 50 and 100 ml vials

5. TARGET SPECIES

Cats and Dogs

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

(see package leaflet)

Cats: as an adjunct in the treatment of upper respiratory tract infections in conjunction with antibiotics.

Dogs: for the treatment of post-operative pain and inflammation.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

(see package leaflet)

1ml/10 kg b.w. by subcutaneous or intramuscular injection in the dog or by subcutaneous route only in the cat. Repeat once after 24 hours if required.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

(see package leaflet)

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Following withdrawal of the first dose, use the product within 28 days. Write the in-use expiry date in the space provided on the carton and label when the container is first broached.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

POM-V

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4048

17. MANUFACTURER’S BATCH NUMBER

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {NATURE/TYPE}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 4% Solution for Injection for Use in Dogs and Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains tolfenamic acid 40mg as active ingredient with benzyl alcohol 10.4mg and sodium formaldehyde sulfoxylate dihydrate 5mg as preservatives

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine 4% Solution for Injection for Use in Dogs and Cats

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains tolfenamic acid 40mg as active ingredient with benzyl alcohol 10.4mg and sodium formaldehyde sulfoxylate dihydrate 5mg as preservatives

4. INDICATION(S)

Cats: Adjuvant treatment of upper respiratory disease in association with antimicrobial therapy.

Dogs: Inflammatory and painful post-operative syndromes.

5. CONTRAINDICATIONS

Tolfenamic acid is contra-indicated in case of cardiac disease.

Do not use in animals with impaired hepatic function or acute renal insufficiency. Tolfenamic acid is contra-indicated in case of ulceration or digestive bleeding, in case of blood dyscrasia or hypersensitivity to tolfenamic acid,

Do not inject intramuscularly in cats.

Do not treat pregnant animals

6. ADVERSE REACTIONS

A temporary increase in thirst and/or diuresis may occur. In most cases, these signs cease spontaneously after treatment. Diarrhoea and vomiting may occur during treatment, where either persists treatment should be discontinued.

Local injection site reactions have been reported following administration of this product.

7. TARGET SPECIES

Cats and Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

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

In cats administration is by the subcutaneous route only.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Protect from light.

Do not store above 25°C

Do not use after the expiry date stated on the carton and vial label after 'EXP'

12. SPECIAL WARNING(S)

<User Warnings>

Take care to avoid accidental self-injection. In case of eye or skin contact, wash immediately with water.

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2023

[It is recommended that the following reference to the VMD Website is included:]

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

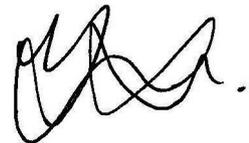
15. OTHER INFORMATION

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.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

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A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 13 October 2023