PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine Tablets 60 mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 60mg tolfenamic acid

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

Box of 1 PVC-aluminium blisters of 8 tablets

Box of 2 PCV-aluminium blisters of 8 tablets

Box of 12 PVC-aluminium blisters of 8 tablets

Box of 24 PVC-aluminium blisters of 8 tablets

Box of 48 PVC-aluminium blisters of 8 tablets

5. TARGET SPECIES

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

(See package leaflet)

4 mg Tolfenamic acid per kg b.w. once daily by oral administration with food for 3 days.

Each 60 mg tablet treats 15 kg bodyweight, once daily.

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

Store in a dry place. Keep blister strips in outer carton.

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

Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08007/4050

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine Tablets 60mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Ltd

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For veterinary use.

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 Ltd
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tolfedine Tablets 60 mg

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

Each tablet contains 60mg tolfenamic acid

4. INDICATION(S)

Cats – In febrile syndrome (abscess, fever of unknown orif=gin)

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 or hypersensitivity to the product.

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.

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.

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.

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 contra-indicated in acute cases of renal insufficiency.

Use in pregnancy

Although studies in laboratory animals did not show any effect on reproduction, it is not advisable to administer the product during gestation.

6. ADVERSE REACTIONS

Undesirable effects and overdose

In case of undesirable effects (anorexia, vomiting, diarrhoea, presence of blood in faeces) occurring during treatment, your veterinarian should be contacted for advice.

Diarrhoea and vomiting may occur in rare cases during the treatment. Moreover, a temporary increase of thirst and/or diuresis may occur. In most cases, these signs cease spontaneously after the treatment.

In case of overdose, administer symptomatic treatment.

7. TARGET SPECIES

Cats and Dogs

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

The recommended dosage is 4mg 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 1/2	2	2 1/2	3						
Number of 60 mg Tablets									1/2	1	1 1/2	2	2 1/2	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 PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach of children

Do not store above 25˚C

12. SPECIAL WARNING(S)

<User Warnings>

In case of accidental contact with eyes, wash with plenty of water.

For Animal Treatment Only

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

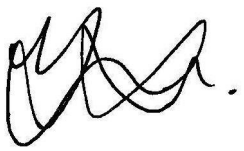
October 2023

[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

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



Approved: 13 October 2023