PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trocoxil 75 mg chewable tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains 75 mg of mavacoxib.

3. PACKAGE SIZE

2 tablets

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister in the outer carton.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5079

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trocoxil chewable tablets

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

75 mg mavacoxib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trocoxil 6 mg chewable tablets for dogs
Trocoxil 20 mg chewable tablets for dogs
Trocoxil 30 mg chewable tablets for dogs
Trocoxil 75 mg chewable tablets for dogs
Trocoxil 95 mg chewable tablets for dogs

2. COMPOSITION

Each chewable tablet contains:

Active substance:

Mavacoxib	6 mg
Mavacoxib	20 mg
Mavacoxib	30 mg
Mavacoxib	75 mg
Mavacoxib	95 mg

Triangular tablet with mottled brown appearance embossed with the tablet strength on one side, the reverse side is blank.

3. TARGET SPECIES

Dogs aged 12 months or more.

4. INDICATIONS FOR USE

Trocoxil chewable tablets are indicated for the treatment of pain and inflammation associated with degenerative joint disease in dogs where treatment for more than one month is needed.

Trocoxil belongs to a group of medicines called Non-steroidal Anti-inflammatory drugs (NSAIDs) which are used to treat pain and inflammation.

5. CONTRAINDICATIONS

Do not use in dogs less than 12 months of age and/or less than 5 kg body weight.
Do not use in dogs suffering from gastro-intestinal disorders including ulceration and bleeding.
Do not use where there is evidence of a haemorrhagic disorder.

Do not use in cases of impaired kidney or liver function.
Do not use in cases of heart insufficiency.
Do not use in pregnant, breeding or lactating animals.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in case of known hypersensitivity to sulphonamides.
Do not use concomitantly with glucocorticoids or other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

6. SPECIAL WARNING(S)

Special warnings:

Do not administer other NSAIDs or glucocorticoids concurrently or within 1 month of the last administration of Trocoxil.

Special precautions for safe use in the target species:

Before prescribing Trocoxil and during treatment with Trocoxil, your veterinarian will check your dog for kidney and liver problems as well as for diseases of the intestines.

Trocoxil should not be used in dehydrated dogs.

If your dog needs surgery, inform the surgeon that the dog is using Trocoxil.

Tell your veterinarian if your dog is using a blood-thinning agent.

Do not exceed the stated dose prescribed by your veterinarian.

Trocoxil has an extended effect duration (up to 2 months after administration of the second dose and following doses). Adverse reactions could occur at any timepoint during this period.

If an adverse reaction to the administration of Trocoxil occurs, stop using the product, and seek medical advice from your veterinarian immediately.

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

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

If you have a known hypersensitivity to NSAIDs you should avoid contact with the veterinary medicinal product.

Ingestion of the product may be harmful for children, and prolonged pharmacological effects leading to e.g. gastrointestinal disorders may be observed. To avoid accidental ingestion, administer the tablet to the dog immediately after removal from the blister packaging.

Do not eat, drink, or smoke when handling the product. Wash hands after handling the product.

Pregnancy and lactation:

Trocoxil must not be used in pregnant, breeding or lactating animals.

Interaction with other medicinal products and other forms of interaction:

How Trocoxil interacts with other medicinal products has not been studied. Tell your veterinarian if your dog receives any other medicinal products. This includes any medicinal products given at least within 24 hours before the first use of Trocoxil and within 1 to 2 months after use. Simultaneous use of medicinal products such as other NSAIDs, glucocorticoids and anticoagulants may increase the risk of adverse events. Your veterinarian will also take into consideration any simultaneous use of medicinal products that are highly bound to plasma proteins in the blood or that may be harmful to the kidneys.

Overdose:

If your dog has received more Trocoxil than it should, contact your veterinarian immediately. Symptoms reported in the overdose studies were symptoms affecting the gastrointestinal system.
Your veterinarian may give general supportive therapy as used for overdose with other NSAIDs. There is no specific antidote for mavacoxib overdose.

7. ADVERSE EVENTS

Dogs aged 12 months or more:

Common (1 to 10 animals / 100 animals treated):
Vomiting, Diarrhoea.
Uncommon (1 to 10 animals / 1,000 animals treated):
Apathy, Appetite loss. Bloody diarrhoea, Melaena. Renal disorder (degradation of renal biochemistry parameters and impaired renal function).*
Rare (1 to 10 animals / 10,000 animals treated):
Gastric ulcer, Small intestine ulcer.

*In rare cases these adverse reactions may be fatal.

If an adverse event following the administration of Trocoxil occurs, no further tablets should be administered and general supportive therapy, as applied to clinical overdose with NSAIDs, should be applied. Particular attention should be paid to maintaining haemodynamic status.

Gastrointestinal protectants and parenteral fluids, as appropriate, may be required for animals that experienced gastrointestinal or renal adverse events. Note that Trocoxil has an extended effect of duration (up to 2 months after administration of the second dose and following doses). Adverse events could occur at any time point during this period.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.

Use the dose prescribed by the veterinarian. The dose of Trocoxil chewable tablets is 2 mg/kg of body weight (see table below).

THIS IS NOT A DAILY TREATMENT.

The initial treatment should be repeated 14 days later, thereafter the dosing interval is one month. A treatment cycle with Trocoxil should not exceed 7 consecutive doses (6.5 months).

Bodyweight (kg)	Number and Strength of Tablets to be Administered				
	6 mg	**20 mg**	**30 mg**	**75 mg**	**95 mg**
5-6	2				
7-10		1			
11-15			1		
16-20		2			
21-23		1	1		
24-30			2		
31-37				1	
38-47					1
45-52			1	1	
53-62			1		1
63-75				2	

9. ADVICE ON CORRECT ADMINISTRATION

Trocoxil should be given immediately before or during the animal's main meal. Care should be taken to ensure that the tablet is ingested.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and 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 or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5076
Vm 42058/5077
Vm 42058/5078
Vm 42058/5079
Vm 42058/5080

Blister packs containing two tablets of the same strength per pack, each tablet containing 6 mg, 20 mg, 30 mg, 75 mg or 95 mg of mavacoxib.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. CONTACT DETAILS

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
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Surrey
KT22 7LP

Manufacturer responsible for batch release:
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Viale Del Commercio 25/27
Ascoli Piceno
63100
Italy

Local representatives and contact details to report suspected adverse reactions:

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Zoetis Belgium
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BE-1930 Zaventem
Tél/Tel: +32 (0) 800 99 189

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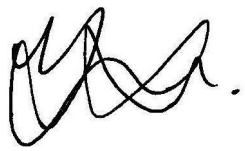

Approved: 05 October 2023