Veterinary medicine package leaflet
This medicine is dispensed with a veterinarian's prescription only
For use in animals only

1. Name, form and strength of the veterinary medicine:
Trocoxil 20 mg Chewable Tablets Veterinary
Trocoxil 30 mg Chewable Tablets Veterinary
Trocoxil 75 mg Chewable Tablets Veterinary
Trocoxil 95 mg Chewable Tablets Veterinary

2. Active ingredient
Each tablet of Trocoxil Veterinary 20 mg contains mavacoxib 20 mg
Each tablet of Trocoxil Veterinary 30 mg contains mavacoxib 30 mg
Each tablet of Trocoxil Veterinary 75 mg contains mavacoxib 75 mg
Each tablet of Trocoxil Veterinary 95 mg contains mavacoxib 95 mg

List of the inactive ingredients in section 13.

3. What is this medicine intended for?
For the treatment of pain and inflammation associated with degenerative joint disease in dogs in cases where continuous treatment exceeding one month is indicated.
Trocoxil veterinary belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) which are used to treat pain and inflammation.

4. Contraindications
Do not use in dogs less than 12 months of age and/or that weigh less than 7 kg.
Do not use in dogs suffering from gastro-intestinal problems, including ulceration and bleeding.
Do not use where there is evidence of bleeding.
Do not use when there is 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 if there is known 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 NSAIDs.
Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity.

5. Adverse reactions
Adverse reactions of the digestive tract such as vomiting and diarrhoea were commonly reported, loss of appetite, haemorrhagic diarrhoea and melaena have been reported in uncommon cases.
Gastrointestinal ulceration was reported in rare cases. Apathy, degradation of renal biochemistry parameters and impaired renal function have been reported in uncommon cases.
In rare cases these adverse reactions may be fatal.
If an adverse reaction following the administration of Trocoxil appears, no further tablets should be administered and general supportive therapy, as applied to clinical overdose with NSAIDs, should be applied. Attention should be paid to maintaining haemodynamic status.
In cases of gastrointestinal or renal adverse reactions, supportive therapy such as gastrointestinal protectants and parenteral fluids may be required.
If the dog suffers from any side effect, including a side effect not mentioned in this leaflet, contact your veterinarian.
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: http://sideeffects.health.gov.il

6. Target animals
Dogs aged 12 months or more.

7. Method of administration and dosage
For oral use.
Use the dose determined by the veterinarian. The dose of Trocoxil Chewable Tablets Veterinary is 2 mg/kg of bodyweight (see table).
This is not a daily treatment.

The initial treatment should be repeated 14 days later, following which the treatment should be administered **once a month**. A treatment cycle with Trocoxil veterinary should not exceed 7 consecutive doses (6.5 months).

Bodyweight (kg)	**Number and Strength of Tablets to be administered**			
	20 mg	**30 mg**	**75 mg**	**95 mg**
7-10	1			
11-15		1		
16-20	2			
21-23	1	1		
24-30		2		
31-37			1	
38-47				1
48-52		1	1	
53-62		1		1
63-75			2	

8. How to use this medicine

Trocoxil Veterinary should be given immediately before or during the dog's main meal. Ensure that the tablet is ingested.

9. Withdrawal period

Not applicable.

10. Warnings

- Special warnings about the safety of using this medicine in animals

Before starting and during treatment with Trocoxil Veterinary, your veterinarian will check your dog for kidney and liver problems as well as for diseases of the intestines.
Trocoxil Veterinary should not be used in dehydrated dogs.
If your dog needs surgery, inform the surgeon that the dog is being treated with Trocoxil Veterinary.
Do not administer other NSAIDs or glucocorticoids concurrently or within at least 1 month of the last administration of Trocoxil Veterinary.
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 during treatment with Trocoxil Veterinary occurs, stop treatment, and consult your veterinarian immediately.
Tell your veterinarian if your dog is being treated with blood-thinning medicines.
Do not exceed the doses prescribed by your veterinarian.

- Special safety precautions for the person administering the medicine

If a person accidentally swallows the medicine, consult a doctor immediately and show them the leaflet or the medicine package.
If you have a known hypersensitivity to NSAIDs, you should avoid contact with the medicine.
Ingestion of Trocoxil Veterinary may be harmful for children, and its prolonged effect can lead to e.g. gastrointestinal disorders. To avoid accidental ingestion, administer the tablet to the dog immediately after removal from the package.
Do not eat, drink, or smoke when handling the medicine. Wash hands after handling the medicine.

- Pregnancy and lactation

Do not use in pregnant, breeding or lactating animals.

11. Storage instructions

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Storage conditions
  Store below 30˚C. Store in the original package.

12. Instructions for the disposal of the unused product or waste materials
Any remaining veterinary medicine or waste obtained from using a veterinary medicine should be disposed of as toxic waste; do not discard into a sewer.

13. Additional information

- **In addition to the active ingredient, this medicine also contains**
  Compressible sugar
  Silicified microcrystalline cellulose
  Croscarmellose sodium
  Sodium laurylsulfate
  Magnesium stearate
  Artificial powdered beef flavour

- **What the medicine looks like and contents of the pack**

Triangular mottled brown tablets embossed with the tablet strength on one side. The package contains one blister with 2 tablets of the same strength.

- **Registration holder**

Zoetis Israel Holding B.V., 5 Atir Yeda st., Kfar Saba

- **Manufacturer's name**

Pfizer Italia S.R.L, Italy
63046 Localita Morino Del Tronto, Ascoli Piceno, Italy

- **Registration number of the medicine in the Ministry of Health's National Drug Registry:**

Trocoxil 20 mg Chewable Tablets Veterinary: 150-15-33567-00
Trocoxil 30 mg Chewable Tablets Veterinary: 150-14-33568-00
Trocoxil 75 mg Chewable Tablets Veterinary: 150-13-33569-00
Trocoxil 95 mg Chewable Tablets Veterinary: 150-12-33570-00

Revised in October 2021 according to MOH guidelines.