

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## **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. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each chewable tablet contains:

### **Active substance:**

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

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Chewable tablets

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

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Dogs aged 12 months or more.

### **4.2 Indications for use, specifying the target species**

For the treatment of pain and inflammation associated with degenerative joint disease in dogs in cases where continuous treatment exceeding one month is indicated.

### **4.3 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 renal or hepatic function  
Do not use in cases of cardiac insufficiency  
Do not use in pregnant, breeding or lactating dogs.  
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), see section 4.8.  
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

#### **4.4 Special warnings for each target species**

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

#### **4.5 Special precautions for use**

##### Special precautions for use in animals

Mavacoxib exhibits an extended plasma half life (up to > 80 days, see section 5.2) due to its low rate of elimination. This corresponds to a duration of effect of 1-2 months after administration of the second dose (and following doses). Care should be taken to avoid treatment of animals that might not tolerate prolonged NSAID exposure. A maximum treatment administration of 6.5 months continuous therapy is recommended so as to manage plasma levels of mavacoxib in animals which exhibit reduced elimination

Animals should undergo a thorough clinical examination before commencing treatment with Trocoxil and appropriate laboratory tests to monitor haematology and clinical chemistry are recommended. Animals with evidence of impaired renal or hepatic function, or with evidence of a protein or blood losing enteropathy are not suitable for treatment with Trocoxil. It is recommended to repeat the clinical examination one month after commencing treatment with Trocoxil and prior to administration of the third dose with additional monitoring of clinical pathology as appropriate during treatment.

Mavacoxib is excreted via bile and in dogs with hepatic disorders reduced elimination and thus excessive accumulation could occur. For this reason, dogs with hepatic disorders should not be treated.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic medicinal products should be avoided.

Ensure appropriate hydration and haemodynamic status when animals receiving Trocoxil undergo anaesthesia and/or surgical procedures or develop conditions which may result in dehydration or compromised haemodynamic status. The key aim of intervention is to maintain renal perfusion. Patients with underlying renal disease may experience exacerbation or decompensation of their renal disease while on NSAID therapy. (See also section 4.6).

##### 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.

Ingestion of Trocoxil 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.

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

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

#### **4.6 Adverse reactions (frequency and seriousness)**

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 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 reactions. Veterinarians should be aware that clinical signs of adverse reactions may continue when supportive therapy (such as gastro protectants) is discontinued.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### **4.7 Use during pregnancy, lactation or lay**

Do not use in pregnant, breeding, or lactating animals. The safety of Trocoxil has not been established during pregnancy and lactation. However, studies in laboratory animals administered other NSAIDs have shown increased pre- and post-implantation loss, embryo-foetal lethality, and malformations.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

No drug interaction studies have been performed. In common with other NSAIDs, Trocoxil should not be administered simultaneously with other NSAIDs or glucocorticosteroids. Risks for interactions have to be accounted for throughout the effect period i.e. 1-2 months after administration of Trocoxil. Dogs should be carefully monitored if Trocoxil is administered simultaneously with an anticoagulant.

NSAIDs are highly bound to plasma proteins and may compete with other highly bound substances, such that concomitant administration may result in toxic effects.

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse effects. To avoid such effects when Trocoxil is to be administered in replacement of another NSAID, ensure an appropriate treatment-free period of at least 24 hours before administering the first dose of Trocoxil. The treatment-free period should however, take into account the pharmacology of the medicinal products used previously. Should another NSAID be administered after Trocoxil treatment, a treatment-free period of at least ONE MONTH should be ensured to avoid adverse effects.

Concurrent administration of potentially nephrotoxic veterinary medicinal products should be avoided.

#### **4.9 Amounts to be administered and administration route**

Oral use.

THIS IS NOT A DAILY NSAID. The dose is 2 mg mavacoxib per kg body weight given immediately before or with the dog's main meal. Care should be taken to ensure that the tablet is ingested. The treatment should be repeated 14 days later, thereafter the dosing interval is ONE MONTH. A treatment cycle 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
48-52			1	1	
53-62			1		1
63-75				2	

#### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In the overdose studies, in common with other NSAIDs, adverse pharmacodynamic events occur affecting the gastrointestinal system. Similarly, adverse reactions occurring at the use dose in the animal population principally involved the gastrointestinal system.

In overdose safety studies, repeated doses of 5 mg/kg and 10 mg/kg were not associated with adverse clinical events, abnormal clinical chemistry or significant histological abnormalities. At 15 mg/kg there was evidence of vomiting and softened/mucoid faeces and an increase in clinical chemistry parameters reflecting renal function. At 25 mg/kg there was evidence of gastrointestinal ulceration.

There is no specific antidote for mavacoxib overdose, but general supportive therapy, as applied to clinical overdose with NSAIDs, should be given.

#### 4.11 Withdrawal period(s)

Not applicable

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids, Coxibs.  
ATCvet code: QM01AH92.

#### 5.1 Pharmacodynamic properties

Mavacoxib is a non-steroidal anti-inflammatory drug (NSAID) of the coxib class. Mavacoxib is 4-[5-(4-fluorophenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]-benzenesulfonamide. It is a diarylsubstituted pyrazole. The principal mode of action is inhibition of cyclooxygenase (COX).

COX is a key enzyme in pathways of arachidonic acid metabolism. Its activity culminates in the synthesis of local hormones and inflammatory mediators, termed eicosanoids, which include several prostaglandins. There are two isoforms of COX, COX-1, and COX-2. COX-1 is a widely distributed constitutive enzyme, primarily involved in maintaining organ and tissue function, whilst COX-2 is

inducible at sites of tissue damage but in some organs, it is also constitutive. COX-2 exerts the major role in synthesising prostaglandins which have pivotal roles as mediators of pain, inflammation and fever. Mavacoxib acts by preferential inhibition of COX-2-mediated prostaglandin synthesis. It therefore possesses analgesic and anti-inflammatory properties. The products of COX-2 metabolism are also involved in ovulation, implantation and closure of the ductus arteriosus. Both COX-1 and COX-2 are present constitutively in the kidney and are assumed to possess protective roles in adverse physiological circumstances.

Based on the results of canine whole blood assays, plasma concentrations producing 20% COX-1 inhibition and 80% COX-2 inhibition were 2.46 µg/mL and 1.28 µg/mL, respectively, so that the IC<sub>20</sub>COX-1:IC<sub>80</sub>COX-2 potency ratio is approximately 2:1, whilst the IC<sub>80</sub>COX-1:IC<sub>80</sub>COX-2 potency ratio is approximately 40:1. These IC concentrations may be compared with mean trough concentrations of mavacoxib in plasma in clinical subjects of 0.52 and 1.11 µg/mL, respectively, after the first and fifth doses. Therefore, clinical doses are predicted to produce low level inhibition of COX-1 and high-level inhibition of COX-2.

## **5.2 Pharmacokinetic particulars**

Mavacoxib is well absorbed after oral administration; bioavailability was 87% in fed dogs and 46 % in fasted conditions and the recommended dose is based on administration with food. Therapeutic concentrations in fed dogs are reached rapidly and peak concentrations are obtained in less than 24 hours after administering a dose. Mavacoxib is approximately 98% bound to plasma proteins. It is extensively distributed throughout the body and almost all the mavacoxib-related residues in plasma comprise parent drug. The rate of body clearance of mavacoxib is slow and the major route of elimination is by biliary excretion of the parent drug.

Multiple-dose pharmacokinetic studies provided no evidence that mavacoxib produces autoinhibition or autoinductive changes in its clearance, and it exhibits linear pharmacokinetics with oral doses ranging from 2 to 50 mg/kg. In laboratory studies with young adult dogs, mean elimination half-life values ranged from 13.8 to 19.3 days. Mavacoxib possessed a longer elimination half-life in client-owned animals. Population pharmacokinetic data derived from studies in dogs with a predominantly older population with heavier dogs as compared to the experimental studies (mean 9 years of age) showed that the mean elimination half-life was 39 days with a small sub-population (<5%) having an elimination half-life of more than 80 days and correspondingly an increased exposure was recorded in these individuals. The reason for this longer half-life is unknown. Steady state pharmacokinetics was attained by the fourth treatment in most animals.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sucrose  
Silicified microcrystalline cellulose  
Artificial powdered beef flavour  
Croscarmellose sodium  
Sodium laurylsulfate  
Magnesium stearate

### **6.2 Major incompatibilities**

Not applicable.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

#### **6.4 Special precautions for storage**

The veterinary medicinal product does not require any special storage conditions.

#### **6.5 Nature and composition of immediate packaging**

Carton boxes containing one blister. Each blister contains two tablets of 6 mg, 20 mg, 30 mg, 75 mg or 95 mg mavacoxib, respectively.

-Blister foil base: PVC film /aluminium foil/ nylon

-Blister backing: vinyl heat seal coating /aluminium foil/polyester film/printable paper

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

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

### **7. MARKETING AUTHORISATION HOLDER**

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

### **8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/08/084/001-005

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 09/09/2008

Date of last renewal: 12/08/2013.

### **10. DATE OF REVISION OF THE TEXT**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

## **ANNEX II**

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**



**A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer(s) responsible for batch release

Pfizer Italia s.r.l.  
Località Marino del Tronto  
63100 Ascoli Piceno (AP)  
ITALY

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

**C. STATEMENT OF THE MRLs**

Not applicable.

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****Carton****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  
Mavacoxib

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 tablet contains 6 mg of mavacoxib.  
1 tablet contains 20 mg of mavacoxib.  
1 tablet contains 30 mg of mavacoxib.  
1 tablet contains 75 mg of mavacoxib.  
1 tablet contains 95 mg of mavacoxib.

**3. PHARMACEUTICAL FORM**

Chewable tablets

**4. PACKAGE SIZE**

2 tablets

**5. TARGET SPECIES**

Dogs

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Oral use. Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)****9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS****12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

**16. MARKETING AUTHORISATION NUMBER(S)**

EU/2/08/084/001 (6 mg)  
EU/2/08/084/002 (20 mg)  
EU/2/08/084/003 (30 mg)  
EU/2/08/084/004 (75 mg)  
EU/2/08/084/005 (95 mg)

**17. MANUFACTURER’S BATCH NUMBER**

Lot

<b>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</b>
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<b>Blister</b>
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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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  
Mavacoxib

<b>2. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
--

Zoetis

<b>3. EXPIRY DATE</b>
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EXP {month/year}

<b>4. BATCH NUMBER</b>
------------------------

Lot

<b>5. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**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**

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

Marketing authorisation holder:

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

Manufacturer responsible for batch release:

Pfizer Italia s.r.l.  
Località Marino del Tronto  
63100 Ascoli Piceno (AP)  
ITALY

**2. 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

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

**Active substance:**

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

Tablets also contain the following ingredients:

Sucrose  
Silicified microcrystalline cellulose  
Artificial powdered beef flavour  
Croscarmellose sodium  
Sodium laurylsulfate  
Magnesium stearate

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



#### **4. INDICATION(S)**

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

#### **7. TARGET SPECIES**

Dogs aged 12 months or more.

## **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
48-52			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**

The veterinary medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp.

## **12. SPECIAL WARNING(S)**

### Advice for dog owner

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.

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

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.

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

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

Do not exceed the stated dose prescribed by your veterinarian.

In case of accidental self-administration, 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 Trocoxil 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

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

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.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

## **15. OTHER INFORMATION**

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.