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

Excipients:

Qualitative composition of excipients and other constituents
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.

3. CLINICAL INFORMATION

3.1 Target species

Dogs aged 12 months or more.

3.2 Indications for use for each 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.

3.3 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 3.8.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Mavacoxib exhibits an extended plasma half life (up to > 80 days, see section 4.3) 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 3.6).

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 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.

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.

Special precautions for the protection of the environment:

Not applicable.

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

3.8 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.

3.9 Administration routes and dosage

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	

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AH92

4.2 Pharmacodynamics

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_{20}COX-1:IC_{80}COX-2 potency ratio is approximately 2:1, whilst the IC_{80}COX-1:IC_{80}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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/084/001-005

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/09/2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

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.
Trocoxil 20 mg chewable tablets.
Trocoxil 30 mg chewable tablets.
Trocoxil 75 mg chewable tablets.
Trocoxil 95 mg chewable tablets.

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. PACKAGE SIZE

2 tablets

4. TARGET SPECIES

 Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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 OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

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)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trocoxil chewable tablets.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

6 mg mavacoxib
20 mg mavacoxib
30 mg mavacoxib
75 mg mavacoxib
95 mg mavacoxib

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

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 warnings

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 and 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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes 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 periods

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.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/08/084/001-005
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

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 and contact details to report suspected adverse reactions:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

België/Belgique/Belgien
Tél/Tel: +32 (0) 800 99 189
pharmvig-belux@zoetis.com

Република България
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Tel: +353 (0) 1 256 9800
pvsupportireland@zoetis.com

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