

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Daxocox 15 mg tablets for dogs  
Daxocox 30 mg tablets for dogs  
Daxocox 45 mg tablets for dogs  
Daxocox 70 mg tablets for dogs  
Daxocox 100 mg tablets for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

### Active substance:

Enflicoxib	15 mg
Enflicoxib	30 mg
Enflicoxib	45 mg
Enflicoxib	70 mg
Enflicoxib	100 mg

### Excipients:

Iron oxide black (E172)	0.26%
Iron oxide yellow (E172)	0.45%
Iron oxide red (E172)	0.50%

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Tablets

Brown, round and convex tablets.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs

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

For the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) in dogs.

### 4.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders, protein or blood losing enteropathy or haemorrhagic disorders.

Do not use in cases of impaired renal or hepatic function.

Do not use in cases of cardiac insufficiency.

Do not use in pregnant or lactating dogs.

Do not use in animals intended for breeding purposes.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in cases of known hypersensitivity to sulphonamides.

Do not use in any dehydrated, hypovolemic 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 Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or glucocorticoids concurrently or within 2 weeks of the last administration of this veterinary medicinal product.

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

##### Special precautions for use in animals

Since the safety of the medicinal product has not been fully demonstrated in very young animals, careful monitoring is advised during the treatment of young dogs aged less than 6 months.

The active metabolite of enflcoxib exhibits an extended plasma half-life due to its low rate of elimination. Use this veterinary medicinal product under strict veterinary monitoring where there is a risk of gastrointestinal ulceration, or if the animal previously displayed intolerance to NSAIDs.

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

This veterinary medicinal product can cause hypersensitivity (allergic) reactions. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

Some NSAIDs may be harmful for the unborn child, especially during the third trimester of pregnancy. Pregnant women should administer this veterinary medicinal product with care.

Ingestion of this veterinary medicinal product may be harmful, especially 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 and do not split or crush tablets.

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

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

Vomiting, soft faeces and/or diarrhoea have been commonly reported in clinical trials, but most cases recovered without treatment.

Apathy, loss of appetite or haemorrhagic diarrhoea have been reported in uncommon cases. Gastrointestinal ulceration has been reported in uncommon cases.

Elevated blood urea and serum cholesterol levels were observed in healthy, young dogs at the recommended dose in a laboratory safety study.

In case of adverse reactions the use of the veterinary medicinal product should be stopped and general supportive therapy, as for clinical overdose with NSAIDs, should be applied until complete resolution of the signs. Particular attention should be paid to maintain haemodynamic status.

Gastrointestinal protectants and parenteral fluids, as appropriate, may be required for animals that experience gastrointestinal or renal adverse reactions.

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**

Laboratory studies in rats and rabbits have shown evidence of foetotoxic effects at maternally toxic doses.

The safety of this veterinary medicinal product has not been established during pregnancy, lactation or reproduction in the target species. Do not use in pregnant, lactating or breeding dogs.

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

No drug-interaction studies have been performed. In common with other NSAIDs, this veterinary medicinal product should not be administered simultaneously with other NSAIDs or glucocorticoids.

Animals should be carefully monitored if this veterinary medicinal product is administered simultaneously with an anticoagulant.

Enflicoxib is 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 reactions. To avoid such adverse reactions when this veterinary medicinal product is to be administered in replacement to another NSAID, ensure an appropriate treatment-free period before administering the first dose. The treatment-free period should, however, consider the pharmacology of the medicinal products previously used.

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

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

Oral use.

Dosing interval is ONCE PER WEEK.

First dose: 8 mg enflicoxib per kg body weight.

Maintenance dose: repeat the treatment every 7 days at the dose of 4 mg enflicoxib per kg body weight.

The veterinary medicinal product should be given immediately before or with the dog's meal. The bodyweight of animals to be treated should be accurately determined to ensure administration of the correct dose.

Body weight (Kg) /Tablet size (mg)	Number of tablets to be administered									
	FIRST DOSE					MAINTENANCE DOSE				
	8 mg/kg					4 mg/kg				
	15 mg	30 mg	45 mg	70 mg	100 mg	15 mg	30 mg	45 mg	70 mg	100 mg
3 - 4.9	2					1				
5 - 7.5		2					1			
7.6 - 11.2			2					1		
11.3 - 15		4					2			
15.1 - 17.5				2					1	
17.6 - 25					2					1
25.1 - 35				4					2	
35.1 - 50					4					2
50.1 - 75					6					3

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

In overdose safety studies at a continuous weekly administration at 12 mg/kg body weight for a period of 7 months and at 20 mg/kg body weight for a period of 3 months, with an initial loading dose, there was evidence of elevated blood urea and serum cholesterol levels. No other associated treatment related effects were detected.

#### 4.11 Withdrawal period

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids, Coxibs.  
ATCvet code: QM01AH95 enflcoxib

#### 5.1 Pharmacodynamic properties

Enflcoxib is a non-steroidal anti-inflammatory drug belonging to the coxib class and acting by selective inhibition of the enzyme cyclooxygenase 2. The cyclooxygenase enzyme (COX) is present in two isoforms. COX-1 is usually a constitutive enzyme expressed in tissues, which synthesize products responsible for normal physiologic functions (e.g. in the gastro-intestinal tract and kidneys), and COX-2 is mainly inducible and synthesized by macrophages and other inflammatory cells after stimulation by cytokines and other mediators of inflammation. COX-2 is involved in the production of mediators, including PGE<sub>2</sub>, that induce pain, exudation, inflammation and fever.

#### 5.2 Pharmacokinetic particulars

Enflcoxib is well absorbed after oral administration; bioavailability is high, and it is increased by 40-50% with food. The recommended dose is based on administration with food. After oral administration to fed dogs at the recommended loading dose of 8 mg/kg bw, enflcoxib is readily absorbed and reaches its maximal concentration of 1.8 ( $\pm$  0.4)  $\mu$ g/ml ( $C_{max}$ ) after 2 hours ( $T_{max}$ ). The elimination half-life ( $t_{1/2}$ ) is 20 h.

Enflcoxib is extensively transformed by the hepatic microsomal system into an active pyrazol metabolite, which reaches its maximal concentration of 1.3 ( $\pm$  0.2)  $\mu$ g/ml ( $C_{max}$ ) after 6 days ( $T_{max}$ ). The elimination half-life ( $t_{1/2}$ ) is 17 days.

Enflicoxib and its active metabolite are extensively bound to dog plasma proteins (98–99%) and are mainly excreted in faeces by the biliary route and, to a lesser extent, in urine.

After repeated administrations, systemic exposure to enflicoxib and its pyrazol metabolite rapidly reaches a plateau, with no evidence of time-dependent pharmacokinetics or over-accumulation for either compound.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Mannitol  
Silicified microcrystalline cellulose  
Sodium laurilsulfate  
Crospovidone  
Crospovidone  
Sodium stearyl fumarate  
Talc  
Iron oxide black (E172)  
Iron oxide yellow (E172)  
Iron oxide red (E172)  
Microcrystalline cellulose  
Dried flavour

### **6.2 Major incompatibilities**

Not applicable.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 30 months

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

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

Store in the original package in order to protect from light.

In order to avoid any accidental ingestion, store tablets out of reach of animals.

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

Blisters are made of a PVC/Aluminium/oriented polyamide blister foil and an aluminium lidding foil.

Package sizes:

Carton boxes containing 4, 10, 12, 20, 24, 50 or 100 tablets.

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**

Ecuphar NV  
Legeweg 157-i  
B-8020  
Oostkamp  
Belgium

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

EU/2/21/270/001-035

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

Date of first authorisation: {DD/MM/YYYY}

**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 responsible for batch release

Lelypharma B.V.  
Zuiveringweg 42  
8243 PZ  
Lelystad  
The Netherlands

**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 BOX**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Daxocox 15 mg tablets for dogs  
Daxocox 30 mg tablets for dogs  
Daxocox 45 mg tablets for dogs  
Daxocox 70 mg tablets for dogs  
Daxocox 100 mg tablets for dogs

Enflicoxib

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:

Enflicoxib 15 mg  
Enflicoxib 30 mg  
Enflicoxib 45 mg  
Enflicoxib 70 mg  
Enflicoxib 100 mg

**3. PHARMACEUTICAL FORM**

Tablets

**4. PACKAGE SIZE**

4 tablets  
10 tablets  
12 tablets  
20 tablets  
24 tablets  
50 tablets  
100 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**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store in the original package in order to protect from light.  
This veterinary medicinal product does not require any special temperature 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**

Ecuphar NV  
Legeweg 157-i  
B-8020 Oostkamp, Belgium

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

EU/2/21/270/001 (15 mg, 4 tablets)  
EU/2/21/270/002 (15 mg, 10 tablets)  
EU/2/21/270/003 (15 mg, 12 tablets)  
EU/2/21/270/004 (15 mg, 20 tablets)  
EU/2/21/270/005 (15 mg, 24 tablets)  
EU/2/21/270/006 (15 mg, 50 tablets)  
EU/2/21/270/007 (15 mg, 100 tablets)  
EU/2/21/270/008 (30 mg, 4 tablets)

EU/2/21/270/009 (30 mg, 10 tablets)  
EU/2/21/270/010 (30 mg, 12 tablets)  
EU/2/21/270/011 (30 mg, 20 tablets)  
EU/2/21/270/012 (30 mg, 24 tablets)  
EU/2/21/270/013 (30 mg, 50 tablets)  
EU/2/21/270/014 (30 mg, 100 tablets)  
EU/2/21/270/015 (45 mg, 4 tablets)  
EU/2/21/270/016 (45 mg, 10 tablets)  
EU/2/21/270/017 (45 mg, 12 tablets)  
EU/2/21/270/018 (45 mg, 20 tablets)  
EU/2/21/270/019 (45 mg, 24 tablets)  
EU/2/21/270/020 (45 mg, 50 tablets)  
EU/2/21/270/021 (45 mg, 100 tablets)  
EU/2/21/270/022 (70 mg, 4 tablets)  
EU/2/21/270/023 (70 mg, 10 tablets)  
EU/2/21/270/024 (70 mg, 12 tablets)  
EU/2/21/270/025 (70 mg, 20 tablets)  
EU/2/21/270/026 (70 mg, 24 tablets)  
EU/2/21/270/027 (70 mg, 50 tablets)  
EU/2/21/270/028 (70 mg, 100 tablets)  
EU/2/21/270/029 (100 mg, 4 tablets)  
EU/2/21/270/030 (100 mg, 10 tablets)  
EU/2/21/270/031 (100 mg, 12 tablets)  
EU/2/21/270/032 (100 mg, 20 tablets)  
EU/2/21/270/033 (100 mg, 24 tablets)  
EU/2/21/270/034 (100 mg, 50 tablets)  
EU/2/21/270/035 (100 mg, 100 tablets)

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Lot {number}

<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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Daxocox 15 mg tablets for dogs  
Daxocox 30 mg tablets for dogs  
Daxocox 45 mg tablets for dogs  
Daxocox 70 mg tablets for dogs  
Daxocox 100 mg tablets for dogs

Enflicoxib

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

Ecuphar NV

<b>3. EXPIRY DATE</b>
-----------------------

EXP {month/year}

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

Lot {number}

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

## **B. PACKAGE LEAFLET**



**PACKAGE LEAFLET:**  
**Daxocox 15 mg tablets for dogs**  
**Daxocox 30 mg tablets for dogs**  
**Daxocox 45 mg tablets for dogs**  
**Daxocox 70 mg tablets for dogs**  
**Daxocox 100 mg 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:

Ecuphar NV  
Legeweg 157-i  
B-8020 Oostkamp, Belgium

Manufacturer responsible for batch release:

Lelypharma B.V.  
Zuiveringweg 42  
8243 PZ  
Lelystad  
The Netherlands

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Daxocox 15 mg tablets for dogs  
Daxocox 30 mg tablets for dogs  
Daxocox 45 mg tablets for dogs  
Daxocox 70 mg tablets for dogs  
Daxocox 100 mg tablets for dogs

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

Each tablet contains:

**Active substance:**

Enflicoxib	15 mg
Enflicoxib	30 mg
Enflicoxib	45 mg
Enflicoxib	70 mg
Enflicoxib	100 mg

**Excipients:**

Iron oxide black (E172)	0.26%
Iron oxide yellow (E172)	0.45%
Iron oxide red (E172)	0.50%

Brown round and convex tablets.

**4. INDICATION(S)**

For the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) in dogs.

## **5. CONTRAINDICATIONS**

Do not use in animals suffering from gastrointestinal disorders, protein or blood losing enteropathy or haemorrhagic disorders.

Do not use in cases of impaired renal or hepatic function.

Do not use in cases of cardiac insufficiency.

Do not use in pregnant or lactating dogs.

Do not use in animals intended for breeding purposes.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in cases of known hypersensitivity to sulphonamides.

Do not use in any dehydrated, hypovolemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

## **6. ADVERSE REACTIONS**

Vomiting, soft faeces and/or diarrhoea have been commonly reported in clinical trials, but most cases recovered without treatment.

Apathy, loss of appetite or haemorrhagic diarrhoea have been reported in uncommon cases.

Gastrointestinal ulceration has been reported in uncommon cases.

Elevated blood urea and serum cholesterol levels were observed in healthy, young dogs at the recommended dose in a laboratory safety study.

In case of adverse reactions the use of the veterinary medicinal product should be stopped and general supportive therapy, as for clinical overdose with NSAIDs, should be applied until complete resolution of the signs. Particular attention should be paid to maintain haemodynamic status.

Gastrointestinal protectants and parenteral fluids, as appropriate, may be required for animals that experience gastrointestinal or renal adverse reactions.

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

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

Oral use.

Dosing interval is ONCE PER WEEK.

First dose: 8 mg enflcoxib per kg body weight.

Maintenance dose: repeat the treatment every 7 days at the dose of 4 mg enflcoxib per kg body weight. The veterinary medicinal product should be given immediately before or with the dog's meal. The bodyweight of animals to be treated should be accurately determined to ensure administration of the correct dose.

	Number of tablets to be administered									
	FIRST DOSE					MAINTENANCE DOSE				
	8 mg/kg					4 mg/kg				
	15 mg	30 mg	45 mg	70 mg	100 mg	15 mg	30 mg	45 mg	70 mg	100 mg
Body weight (Kg) /Tablet size (mg)										
3-4.9	2					1				
5-7.5		2					1			
7.6-11.2			2					1		
11.3-15		4					2			
15.1-17.5				2					1	
17.6-25					2					1
25.1-35				4					2	
35.1-50					4					2
50.1-75					6					3

## 9. ADVICE ON CORRECT ADMINISTRATION

## 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 temperature storage conditions.

Store in the original package in order to protect from light.

In order to avoid any accidental ingestion, store tablets out of reach of animals.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNING(S)

Special warnings for each target species:

Do not administer other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or glucocorticoids concurrently or within 2 weeks of the last administration of this veterinary medicinal product.

Special precautions for use in animals:

Since the safety of the medicinal product has not been fully demonstrated in very young animals, careful monitoring is advised during the treatment of young dogs aged less than 6 months.

The active metabolite of enflcoxib exhibits an extended plasma half-life due to its low rate of elimination. Use this veterinary medicinal product under strict veterinary monitoring where there is a risk of gastrointestinal ulceration, or if the animal previously displayed intolerance to NSAIDs.

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

This veterinary medicinal product can cause hypersensitivity (allergic) reactions. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

Some NSAIDs may be harmful for the unborn child, especially during the third trimester of pregnancy. Pregnant women should administer this veterinary medicinal product with care.

Ingestion of this veterinary medicinal product may be harmful, especially 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 and do not split or crush tablets.

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

#### Pregnancy and lactation:

Laboratory studies in rats and rabbits have shown evidence of foetotoxic effects at maternally toxic doses.

The safety of this veterinary medicinal product has not been established during pregnancy, lactation or reproduction in the target species. Do not use in pregnant, lactating or breeding dogs.

#### Interaction with other medicinal products and other forms of interaction:

No drug-interaction studies have been performed. In common with other NSAIDs, this veterinary medicinal product should not be administered simultaneously with other NSAIDs or glucocorticoids.

Animals should be carefully monitored if this veterinary medicinal product is administered simultaneously with an anticoagulant.

Enflcoxib is 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 reactions. To avoid such adverse reactions when this veterinary medicinal product is to be administered in replacement to another NSAID, ensure an appropriate treatment-free period before administering the first dose. The treatment-free period should, however, consider the pharmacology of the medicinal products previously used.

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

#### Overdose (symptoms, emergency procedures, antidotes):

In overdose safety studies at a continuous weekly administration at 12 mg/kg body weight for a period of 7 months and at 20 mg/kg body weight for a period of 3 months, with an initial loading dose, there was evidence of elevated blood urea and serum cholesterol levels. No other associated treatment related effects were detected.

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

Ask your veterinary surgeon or pharmacist 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**

Carton boxes containing 4, 10, 12, 20, 24, 50 or 100 tablets.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**België/Belgique/Belgien**

Ecuphar NV  
Legeweg 157-i  
B-8020 Oostkamp  
Tél/Tel: +32 50314269

**Lietuva**

VIRBAC  
1<sup>re</sup> avenue 2065 m LID  
FR-06516, Carros  
Tel: +33-(0)492087300

**Република България**

VIRBAC  
1<sup>re</sup> avenue 2065 m LID  
FR-06516, Carros  
Tel: +33-(0)492087300

**Luxembourg/Luxemburg**

Ecuphar NV  
Legeweg 157-i  
B-8020 Oostkamp  
Tel: +32 50314269

**Česká republika**

VIRBAC  
1<sup>re</sup> avenue 2065 m LID  
FR-06516, Carros  
Tel: +33-(0)492087300

**Magyarország**

VIRBAC HUNGARY KFT  
Szent István krt.11.II/21.  
HU-1055 Budapest  
Tel: +36 703387177

**Danmark**

VIRBAC Danmark A/S  
Profilvej 1  
DK-6000 Kolding  
Tel: +45 75521244

**Malta**

AGRIMED LIMITED  
MDINA ROAD, ZEBBUG ZBG 9016, MALTA  
Tel: +356 21465797

**Deutschland**

Ecuphar GmbH  
Brandteichstraße 20  
DE-17489 Greifswald  
Tel: +49 3834835840

**Nederland**

Ecuphar BV  
Verlengde Poolseweg 16  
NL-4818 CL Breda  
Tel: +31 880033800

**Eesti**

VIRBAC  
1<sup>re</sup> avenue 2065 m LID  
FR-06516, Carros  
Tel: +33-(0)492087300

**Norge**

VIRBAC Danmark A/S  
Profilvej 1  
DK-6000 Kolding  
Tel: +45 75521244

**Ελλάδα**

ΧΕΛΛΑΦΑΡΜ ΑΕ  
1<sup>ο</sup> χλμ. Λεωφόρου Παιανίας – Μαρκοπούλου,  
19002, ΤΘ 100, Παιανία, Ελλάδα  
Τηλ.: +30 2106800900

**Österreich**

VIRBAC Österreich GmbH  
Hildebrandgasse 27  
A-1180 Wien  
Tel: +43-(0)121834260

**España**

Ecuphar Veterinaria SLU  
C/Cerdanya, 10-12 Planta 6<sup>o</sup>  
ES- 08173 Sant Cugat del Vallés,  
Barcelona  
Tel: +34 935955000

**Polska**

VIRBAC Sp. z o.o.  
ul. Puławska 314  
PL 02-819 Warszawa  
Tel.: +48 228554046

**France**

VIRBAC France  
13<sup>e</sup> rue LID  
FR-06517, Carros  
Tel: +33 (0)805055555

**Portugal**

Belphar Lda  
Sintra Business Park 7, Edifício 1, Escritório 2K  
Zona Industrial de Abrunheira  
PT-2710-089 Sintra  
Tel: +351 308808321

**Hrvatska**

VIRBAC  
1<sup>re</sup> avenue 2065 m LID  
FR-06516, Carros  
Tel: +33-(0)492087300

**România**

VIRBAC  
1<sup>re</sup> avenue 2065 m LID  
FR-06516, Carros  
Tel: +33-(0)492087300

**Ireland**

Ecuphar NV  
Legeweg 157-i  
B-8020 Oostkamp  
Tel: +32 50314269

**Slovenija**

VIRBAC  
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