LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Daxocox 30 mg tablets for dogs
Enflicoxib

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Enflicoxib 30 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)

Vm 32742/5002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Daxocox 30 mg tablets for dogs
Enflicoxib

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ecuphar NV

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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 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.

	Number of tablets to be administered									
	FIRST DOSE 8 mg/kg					**MAINTENANCE DOSE** 4 mg/kg				
Body weight (Kg) /Tablet size (mg)	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

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 enflicoxib 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.

Enflixcoxib 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

February 2023

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.

United Kingdom (Great Britain)
Animalcare Ltd
Moorside
Monks Cross
York, YO32 9LB
United Kingdom

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