PARTICULARS TO APPEAR ON THE OUTER PACKAGE { CARTON BOX }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Daxocox 200 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Enflicoxib 200 mg

3. PACKAGE SIZE

4 tablets
5 tablets
12 tablets
20 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

Keep the blisters in the outer carton. in order to protect from light.

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

Ecuphar
An Animalcare Company

14. MARKETING AUTHORISATION NUMBERS

Vm 32742/5008

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Daxocox

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

200 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE 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
Daxocox 140 mg tablets for dogs
Daxocox 200 mg tablets for dogs

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
Daxocox 140 mg tablets for dogs
Daxocox 200 mg tablets for dogs

2. Composition

Each tablet contains:

Active substances:

Enflicoxib	15 mg
Enflicoxib	30 mg
Enflicoxib	45 mg
Enflicoxib	70 mg
Enflicoxib	100 mg
Enflicoxib	140 mg
Enflicoxib	200 mg

Excipients:

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

Brown, round and convex or capsule shaped tablets.

3. Target species

Dogs

4. Indications for use

For the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease).
For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery.

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. Special warnings

Special warnings:

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 safe use in the target species:

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, lactation and fertility:

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or reproduction in the target species.

Pregnancy and lactation:
Do not use during pregnancy or lactation
Laboratory studies in rats and rabbits have shown evidence of foetotoxic effects at maternally toxic doses.

Fertility:
Do not use in breeding animals.

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.

Overdose:

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.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Vomiting (1), Diarrhoea (1), Soft stool (1)
Uncommon (1 to 10 animals / 1 000 animals treated):	Apathy, Appetite loss Haemorrhagic diarrhoea, Gastric ulcer
Undetermined frequency (cannot be estimated from the available data)	Elevated blood urea nitrogen (BUN), Elevated cholesterol (total)

(1) Most cases recover without treatment.

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.

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 or its local representative using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.
Dosing interval is ONCE PER WEEK.

Osteoarthritis:

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.

	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	140 mg	200 mg	15 mg	30 mg	45 mg	70 mg	100 mg	140 mg	200 mg
2.5 - 4.9	2							1						
5 - 7.5		2							1					
7.6 – 11.2			2							1				
11.3 - 17.5				2							1			
17.6 - 25					2							1		
25.1 - 35						2							1	
35.1 - 50							2							1
50.1 - 75						4							2	

For perioperative use:
A single treatment at a dose of 8 mg per kg body weight must be administered one day (at least 24 hours) before surgery is scheduled. If, at 7 days after the initial treatment (6 days post-surgery), the treating veterinarian determines that further post-operative analgesia is necessary, subsequent treatments may be administered at a dose of 4 mg per kg body weight and at a 7-day treatment interval.

To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

The veterinary medicinal product should be given immediately before or with the dog's meal.

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 temperature storage conditions.

Keep the blisters in the outer carton 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 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.

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 or pharmacist 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

Vm 32742/5001
Vm 32742/5002
Vm 32742/5003
Vm 32742/5004
Vm 32742/5005
Vm 32742/5007
Vm 32742/5008

Carton boxes containing 4, 5, 10, 12, 20, 24, 50 or 100 tablets for Daxocox 15, 30, 45, 70 and 100 mg.
Carton boxes containing 4, 5, 12 and 20 tablets for Daxocox 140 and 200 mg.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Ecuphar NV
Legeweg 157-i
8020 Oostkamp
Belgium

Manufacturer responsible for batch release:
Lelypharma B.V.
Zuiveringweg 42
8243 PZ
Lelystad
The Netherlands

Local representatives and contact details to report suspected adverse events:

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

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

17. Other information

POM-V

Gavin Hall

Approved: 04 March 2026