SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Daxocox 70 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Enflicoxib 70 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Mannitol	
Silicified microcrystalline cellulose	
Sodium laurilsulfate	
Crospovidone	
Copovidone	
Sodium stearyl fumarate	
Talc	
Iron oxide black (E172)	0.26%
Iron oxide yellow (E172)	0.45%
Iron oxide red (E172)	0.50%
Microcrystalline cellulose	
Dried flavour	

Brown, round and convex tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

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.

3.3 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.

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative 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

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.

3.8 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.

3.9 Administration routes and dosage

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.

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

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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: QM01AH95

4.2 Pharmacodynamics

Enflicoxib 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 PGE2, that induce pain, exudation, inflammation and fever.

4.3 Pharmacokinetics

Enflicoxib 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, enflicoxib is readily absorbed and reaches its maximal concentration of 1.8 (± 0.4) mcg/ml (Cmax) after 2 hours (Tmax). The elimination half-life (t1/2) is 20 h. Enflicoxib is extensively transformed by the hepatic microsomal system into an active pyrazol metabolite, which reaches its maximal concentration of 1.3 (± 0.2) mcg/ml (Cmax) after 6 days (Tmax). The elimination half-life (t1/2) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

5.3 Special precautions for storage

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.

5.4 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, 5, 10, 12, 20, 24, 50 or 100 tablets.

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.

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

Ecuphar NV

7. MARKETING AUTHORISATION NUMBER

Vm 32742/5004

8. DATE OF FIRST AUTHORISATION

01 April 2021

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

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 04 March 2026