Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Daxocox 140 mg Tablets for Dogs
Daxocox 200 mg Tablets for Dogs

Date Created: September 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Daxocox 140 mg Tablets for Dogs, Tablet Daxocox 200 mg Tablets for Dogs, Tablet
Applicant	Ecuphar NV, Legeweg 157-i, 8020 Oostkamp, Belgium
Active substance	Enflicoxib
ATC Vetcode	QM01AH95
Target species	Dogs
Indication for use	For the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) in dogs.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 8 of VMRs 2013 (Schedule 1, Part 1) as amended.
Date of conclusion of the procedure	30/06/2025

I. SCIENTIFIC OVERVIEW

The product was submitted for a full application in accordance with Article 8 of VMRs 2013 (Schedule 1, Part 1) as amended. The applications are to extend the Daxocox product range to include two additional tablet sizes in addition to the current 15mg, 30mg, 45mg, 70mg and 100mg strengths.

The new product strengths of Daxocox tablets contain 140mg and 200mg enflicoxib. The products are indicated for the treatment of pain and inflammation associated with osteoarthritis (or degenerative joint disease) in dogs. When starting the product, the dose for the first administration is 8 mg/kg and following this the maintenance dose is 4mg/kg. The dosing interval is one week and the product should be given immediately before or with food.

The product is classified as POM-V, a veterinary medicinal product subject to prescription.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC[1]. The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains enflicoxib and the excipients mannitol, silicified microcrystalline cellulose, sodium laurilsulfate, crospovidone, copovidone,

[1] SPC – Summary of Product Characteristics.
[2] Efficacy – The production of a desired or intended result.

sodium stearyl fumarate, talc, iron oxide black (E172), iron oxide yellow (E172), iron oxide red (E172), microcrystalline cellulose and dried flavour.

The container/closure system consists of aluminium/aluminium blisters in a standard carton box. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is enflicoxib, a novel active substance, as used in the authorised smaller tablet sizes. The relevant Active Substance Master File (ASMF) is provided.

The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

The excipients that are contained in a pharmacopoeia comply with their relevant monographs. The dried flavour ingredient fully complies with EC flavouring regulation (EC) No1334/2008, Regulation (EC) No 2065/2003 and Regulation (EC) No 1333/2008.

The packaging materials used all comply with the relevant guidelines and regulations.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the Transmissible spongiform encephalopathy (TSE) Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form.

The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the production site have been provided, demonstrating compliance with the specification.

Control tests on the finished product are those appropriate for this type of dosage form.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life, when stored under the approved conditions.

G. Other Information

The shelf life of the product as packaged for sale is 4 years.

The product does not require any special temperature storage conditions. It should be stored in the original package to protect from light. To avoid any accidental ingestion, store tablets out of reach of animals.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

No new pharmacological data have been provided, which is acceptable as these are extension applications. Pharmacological information on the active substance can be taken from data on the already authorised products.

Enflicoxib is a non-steroidal anti-inflammatory drug belonging to the coxib class and acting by selective inhibition of the enzyme cyclooxygenase 2 (COX-2). COX 2 is involved in the production of mediators that induce pain, exudation, inflammation and fever.

Enflicoxib is well absorbed after oral administration; bioavailability is high, and it is increased by 40-50% when given with food. The recommended dose is based on administration with food. After oral administration to fed dogs at the recommended loading dose enflicoxib is readily absorbed and reaches its maximal concentration after 2 hours. The elimination half-life is 20 hours.

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 metabolite rapidly reaches a plateau, with no evidence of time-dependent pharmacokinetics or over-accumulation for either compound.

Toxicological Studies

No new toxicological data have been provided, which is acceptable as these are extension applications. A summary of the toxicity data from the authorised product strengths was provided.

User Safety

The user risk assessment was determined to be the same as for the authorised smaller product strengths, where it was provided in compliance with the relevant guideline. Risks to the user are unchanged from the original assessment of the smaller tablet sizes.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- This 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 the product with care.
- Ingestion of this 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.

Environmental Safety

No new Environmental Risk Assessment (ERA) was provided as it is the same as for the authorised smaller product strengths.

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

Due to the applications being extensions of the current Daxocox range, no new data was submitted for clinical efficacy.

IV.I. Pre-Clinical Studies

Pharmacology

The clinical trials submitted for the original authorisation used a 120mg tablet to demonstrate efficacy. To demonstrate bioequivalence to this*, in vitro* dissolution testing results were used to compare this 120mg strength to the new 140mg and 200mg tablet sizes.

Results indicated similarity of dissolution profiles between the 120 mg tablet and the two new tablet strengths at all three investigated pH values of 1.2, 4.5 and 7.5. Overall, it was concluded that the two new tablet strengths are bioequivalent to the 120 mg tablet.

Tolerance in the Target Species

Tolerance studies were not required because this is an extension of the Daxocox range and data on the authorised products could be used to demonstrate safety in dogs.

IV.II. Clinical Documentation

It can be concluded that the efficacy of the two new product strengths is the same as the original authorised products, as bioequivalence was adequately demonstrated. Consequently, no new *in vivo* data was required and the effectiveness of the products in the target species for the specified indications was accepted.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that, when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the products is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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