MINISTERIO DE SANIDAD
agencia española de medicamentos y productos sanitarios

DEPARTAMENTO DE MEDICAMENTOS VETERINARIOS

# Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
**(Reference Member State)**

## PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

**Duecoxin 10 mg chewable tablets for dogs**

CORREO ELECTRÓNICO
mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443

# PRODUCT SUMMARY

| | |
|---|---|
| EU procedure number | ES/V/0441/002/DC |
| Name, strength and pharmaceutical form | Duecoxin 10 mg chewable tablets for dogs |
| Applicant | Fatro S.p.A.<br>Via Emilia, 285<br>40064 Ozzano dell' Emilia (Bologna)<br>Italy |
| Active substance(s) | Robenacoxib |
| ATC vetcode | QM01AH91 |
| Target species | Dogs |
| Indication for use | For the treatment of pain and inflammation associated with chronic osteoarthritis.<br>For the treatment of pain and inflammation associated with soft tissue surgery. |

## PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

# SUMMARY OF ASSESSMENT

| | |
|---|---|
| Legal basis of original application* | Generic application in accordance with Article 18 of Regulation (EU) 2019/6. |
| Reference product (RP) | Onsior 10 mg tablets for dogs |
| Marketing authorisation holder | Elanco GmbH |
| MS where the RP is or has been authorised | UE |
| Marketing authorisation number | - |
| EU procedure number | EU/2/08/089/008 |
| Date of authorisation | December 2008 |
| Date of completion of the original decentralised procedure | Day 210: 18/12/2024 |
| Date veterinary medicinal product first authorised in the Reference Member State (MRP only) | - |
| Concerned Member States for original procedure | AT, BE, CZ, DE, DK, EL, FI, HR, HU, IT, NO, PL, PT, SE, SK |
| Withdrawn CMS during original decentralised procedure | - |

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

# 1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

# 2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

## 2.A. Product description

The VMP contains robenacoxib and starch, pregelatinised, yeast powder, povidone K-30 (E1201), magnesium stearate, silica, colloidal anhydrous (E551), crospovidone (E1202), artificial liver flavour, cellulose, microcrystalline (E460).

The container/closure system is in PVC/PE/PVdC/PE/PVC sealed with thermoheated aluminum foil.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

## 2.B. Description of the manufacturing method

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

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

## 2.C. Production and control of starting materials

The active substance is Robenacoxib, an established active substance not described in the European Pharmacopeia/National pharmacopeia of a member state/pharmacopeia of a third country. 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.

Satisfactory TSE information has been provided in compliance with the current Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.

### 2.D. Control tests carried out on isolated intermediates during the manufacturing process

*NA*

### 2.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 VMP.

Satisfactory validation data for the analytical methods have been provided.

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

### 2.F. Stability tests

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

### 2.G. Other information

NA

## 3. SAFETY DOCUMENTATION (safety and residues tests)

### 3.A. Safety tests

***Pharmacological studies***

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with reference VMP has been demonstrated, results of pharmacological tests are not required.

***Toxicological studies***

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

***User safety***

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the most likely route of contact with the veterinary medicinal product is dermal exposure. Accidental ingestion may occur if a child comes into contact with the veterinary medicinal product.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

***Environmental Risk Assessment***

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will only be used in non-food animals.

### 3.B. Residues documentation

Not applicable.

## 4. EFFICACY DOCUMENTATION

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

## 5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

## POST-AUTHORISATION PROCEDURES

None.