IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Robenord

PRODUCT SUMMARY

EU Procedure number	IE/V/0641/001/DC
Name, strength and pharmaceutical form	Robenord 20 mg/ml solution for injection for cats and dogs
Active substance(s)	Robenacoxib
Applicant	Accord Healthcare B.V., Winthontlaan 200, Utrecht, 3526KV, Netherlands.
Target species	Dogs and cats
Indication(s) for use	For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery.
ATCvet code	QM01AH91
Legal basis of original application	Generic application in accordance with Article 18 of Regulation (EU) 2019/6 as amended.
Reference product (RP) Marketing authorisation holder Marketing authorisation number EU procedure number Date of authorisation	Onsior 20 mg/ml solution for injection Elanco GmbH, Germany EU/2/08/089/020 EMEA/V/C/000127 16/12/2008
Date of completion of the original procedure	12/02/2026
Concerned Member States for original procedure	BE, DE, ES, FR, IT, NL, PL, UK(NI).

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

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

I. SCIENTIFIC OVERVIEW

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; the slight reactions observed following administration are indicated in the SPC.

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 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. QUALITY ASPECTS

A. Product description

The product contains robenacoxib (20 mg/ml) and the excipients macrogol 400, ethanol anhydrous E1510, poloxamer 188, sodium metabisulphite E223, sodium hydroxide, citric acid monohydrate and water for injections.
The container/closure system is standard for this dosage form and is described in the SPC. The choice of the formulation and presence of preservatives are justified. The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product Description of the manufacturing method
The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site. Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials Production and control of starting materials
The active substance is an established active substance. 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 has been provided.

D. Control tests carried out on isolated intermediates during the manufacturing process
Not applicable.

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

F. Stability tests (pharmaceuticals)
Stability data on the active substance has been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.
Stability data on the finished product has been provided in accordance with applicable European guidelines, demonstrating the stability and in-use stability of the veterinary medicinal product throughout its shelf life when stored under the approved conditions.

G. Other Information (pharmaceuticals)
Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application for 'Robenord 20 mg/ml solution for injection for cats and dogs,' containing the active substance robenacoxib, was submitted in accordance with the requirements of Article 18 of Regulation (EU) 2019/6 (that is, a generic application). The reference veterinary medicinal product (VMP) cited is 'Onsior 20 mg/ml solution for injection' (EU/2/08/089/020), which is authorised through the centralised procedure and is accepted as a suitable reference product.

The applicant has claimed a waiver from bioequivalence study requirements (to demonstrate *in vivo* bioequivalence) based on compliance with the conditions set out in Section 7.1 b) of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev. 4). These conditions have been fulfilled; therefore the omission of documentation on safety and efficacy is deemed to be acceptable.

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

The safety aspects of this product are identical to the reference VMP.

Warnings and precautions as listed on the product literature are in line with those of the reference VMP and are adequate to ensure safety of the product to users and the environment.

III. SAFETY ASSESSMENT

III.A Safety Tests

Pharmacological Studies

No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference VMP has been accepted, results of pharmacological tests are not required**.**

However, in support of this application a brief overview of the pharmacological profile of robenacoxib as available from published literature was presented.
The text relating to pharmacodynamics and pharmacokinetics in Sections 4.2 and 4.3 of the SPC is identical to that approved for the reference product. This is considered acceptable.

Toxicological Studies

No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference VMP has been accepted, results of toxicological tests are not required.

User Safety

A brief user safety assessment was provided, and it is accepted that the text proposed for inclusion in Section 3.5 of the SPC is appropriate and that the warning statements will mitigate any risk to users.

It is accepted that the candidate product does not pose any greater risk to the user than the reference product, and as such, the user safety warnings as approved for the reference product are considered applicable for 'Robenord 20 mg/ml solution for injection for cats and dogs.'

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product, as follows:

'*For pregnant women, particularly near-term pregnant women, accidental injection and prolonged dermal exposure increases the risk for premature closure of the ductus arteriosus in the foetus.*

Wash hands and exposed skin immediately after use of the veterinary medicinal product.
In case of accidental oral exposure (hand-to-mouth), prolonged dermal exposure or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.'

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.
Phase I:
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.
Conclusion
Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

IV. CLINICAL ASSESSMENT

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

IV.A Pre-Clinical Studies

Pharmacology

No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference VMP has been accepted, results of pharmacological tests are not required.

Tolerance in the Target Species of Animals

No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference VMP has been accepted, results of target animal safety tests are not required**.**

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical trials

No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence can be accepted in accordance with the criteria laid out in Section 7.1b) of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4), the results of efficacy tests are not required. The clinical efficacy profile of the candidate product is not expected to differ from that of the reference product formulation.

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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 in the Union Product Database (UPD).

This section 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.

Changes:
None.