IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Maropicord

PRODUCT SUMMARY

EU Procedure number	IE/V/0634/001/DC
Name, strength and pharmaceutical form	Maropicord 10 mg/ml solution for injection for dogs and cats
Active substance(s)	Maropitant citrate monohydrate
Applicant	Accord Healthcare B.V., Winthontlaan 200, Utrecht, 3526KV, Netherlands.
Target species	Dogs and cats
Indication(s) for use	Dogs • For the treatment and prevention of nausea induced by chemotherapy. • For the prevention of vomiting except that induced by motion sickness. • For the treatment of vomiting, in combination with other supportive measures. • For the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the μ-opiate receptor agonist morphine. Cats • For the prevention of vomiting and the reduction of nausea, except that induced by motion sickness. • For the treatment of vomiting, in combination with other supportive measures.
ATCvet code	QA04AD90

SUMMARY OF ASSESSMENT

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	Cerenia 10 mg/ml solution for injection for dogs and cats. Zoetis Belgium EU/2/06/062/005 EMEA/V/C/000106 29/09/2006
Date of completion of the original decentralised procedure	11/02/2026
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; reactions which may be 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 maropitant citrate monohydrate (14.48 mg) and the excipients sulfobutylbetadex sodium, metacresol (3.3 mg) 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 preservative 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)

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 of the 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 'Maropicord 10 mg/ml solution for injection for dogs and cats,' containing the active substance maropitant citrate monohydrate, 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 'Cerenia 10 mg/ml solution for injection for dogs and cats' (EU/2/06/062/005), which is authorised through the centralised procedure and is accepted as a suitable reference product.

The applicant has claimed waivers from bioequivalence study requirements (to demonstrate *in vivo* bioequivalence) based on compliance with the conditions set out in sections 7.1 a) and 7.1 b) of the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4) for the intravenous and subcutaneous routes of administration respectively. 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 largely reflective of 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 maropitant citrate monohydrate 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 may also be considered applicable for 'Maropicord 10 mg/ml solution for injection for dogs and cats.' However, some updates were made to bring the wording in line with that approved for similar products authorised through the decentralised procedure.

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

'*Maropitant is a neurokinin-1 (NK1) receptor antagonist that acts in the central nervous system. The veterinary medicinal product may therefore cause nausea, dizziness and drowsiness in case of accidental self-injection. If accidental self-injection occurs, seek medical advice immediately and show the package leaflet or the label to the physician.*

The veterinary medicinal product may cause skin sensitization. People with known hypersensitivity to maropitant should avoid contact with the veterinary medicinal product. Wash exposed skin immediately after exposure with large amounts of water. If you develop symptoms such as a rash after accidental exposure, seek medical advice and show the physician this warning.

The veterinary medicinal product may cause eye irritation. Eye contact is absolutely to be avoided. In case of accidental exposure, flush eyes with plenty of water and seek medical attention immediately.

Wash hands after use.'

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 sections 7.1a) and b) of the CVMP 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.
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.