IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Apovomin 3 mg/ml solution for injection for dogs

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PRODUCT SUMMARY

Name, strength and pharmaceutical form	Apovomin 3 mg/ml solution for injection for dogs
Active substance(s)	Apomorphine hydrochloride hemihydrate
Applicant	Dechra Regulatory B.V. Handelsweg 25 5531 AE Bladel The Netherlands
Legal basis of application	Article 13(1) of Directive 2001/82/EC as amended
Date of Authorisation	16th March 2018
Target species	Dogs
Indication for use	Induction of emesis.
ATCvet code	QN04BC07
Concerned Member States	AT, BE, BG, CY, CZ,DE, DK, EE, EL, ES, FI, FR, HR, HU, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE,SI, SK, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the 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 Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. 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) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

This application was submitted by Dechra Regulatory B.V. The candidate product is Apovomin 3 mg/ml solution for injection for dogs and contains apomorphine hydrochloride hemihydrate as active substance.

This application has been submitted in accordance with paragraph 1 of Article 13 of Directive 2001/82/EC, as amended (application for a generic veterinary medicinal product).

The reference product cited in this application is Delta Apomorphine Hydrochloride Solution for Injection 3 mg/ml (VPA 10793/001/001) which was first authorised in Ireland on 08/02/2002 in accordance with Article 12.3 (full dossier).
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 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.

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II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains 3 mg/ml apomorphine hydrochloride hemihydrate (equivalent to 2.56 mg/ml apomorphine) and the excipients benzyl alcohol (E1519), sodium metabisulfite (E 223), sodium chloride, water for injections, sodium hydroxide and hydrochloric acid, diluted.

The product is packaged in a clear Type I glass vials containing 5, 10 or 20 ml, closed with a coated bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box.

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

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

The active substance is apomorphine hydrochloride hemihydrate, an established substance described in the European Pharmacopoeia. 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.

Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on Intermediate Products

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

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.

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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

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of safety tests are not required. As the product is not indicated for use in food-producing species, residues data is not required.

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

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

III.A Safety Testing

Pharmacological Studies

Apomorphine induces emesis by stimulation of the dopamine D2-receptors in the chemoreceptor trigger zone (CTZ). Apomorphine may lower blood pressure.

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of pharmacological studies were not required.

Toxicological Studies

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of toxicological studies were not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that systemic exposure is most likely to arise following accidental self-injection and exposure via other routes are not of concern.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. It can be accepted that the product will not present an unacceptable risk to the user when handled, administered stored and disposed of in accordance with the recommendations included in the proposed SPC.

Environmental Risk Assessment

Phase I

The product will only be used in non-food producing animals and therefore the environmental risk assessment may stop in Phase I.

It was concluded that the product will not present an unacceptable risk for the environment when handled, administered, stored and disposed of in accordance with the recommendations included in the proposed SPC.

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III.B Residues Documentation

Not applicable.

IV. CLINICAL ASSESSMENT

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of efficacy studies are not required.

The efficacy aspects of this product are considered to be identical to the reference product.

IV.A Pre-Clinical Studies

Pharmacology

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of pharmacological studies were not required.

Tolerance in the Target Species of Animals

This is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated.

The product is to be administered to the same target species using the same dose rate and route of administration as already approved for the reference product. Given the similarity in formulation with the reference product, it was accepted that the product will not present an unacceptable risk in terms of target animal tolerance.

Consequently, tolerance study data was not required.

IV.B Clinical Studies

Laboratory Trials
Field Trials

As this is a generic application according to paragraph 1 of Article 13 of Directive 2001/82/EC and bioequivalence with a reference product has been demonstrated, results of laboratory and field trials were not required.

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 on the HPRA website.

This section contains information on

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significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

None

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