IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Geepenil vet 6.36 g powder for solution for injection

PRODUCT SUMMARY

EU Procedure number	IE/V/0671/001/DC
Name, strength and pharmaceutical form	Geepenil vet 6.36 g powder for solution for injection
Active substance(s)	Benzylpenicillin sodium
Applicant	Orion Corporation Orionintie 1 FI-02200 Espoo Finland
Target species	Horses
Indication(s) for use	Treatment of infections caused by micro-organisms susceptible to benzylpenicillin.
ATCvet code	QJ01CE01

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 MS where the RP is or has been authorised Marketing authorisation number Date of authorisation	Novocillin vet 6.3g Powder and solution for solution for injection Boehringer Ingelheim Vetmedica Sweden 94533 21/12/1992
Date of completion of the original decentralised procedure	06/03/2026
Concerned Member States for original procedure	AT, BE, DE, FR, LU, NL

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 are indicated in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals 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 the active substance benzylpenicillin sodium at 6.36 g/ vial. The container/closure system is standard for this dosage form and is described in the SPC.

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 benzylpenicillin sodium, an established active substance described in the European/ /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 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 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
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.

G. Other Information
Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 (generic veterinary medicinal product).
The applicant has cited a suitable reference product which has been authorised for in excess of ten years and can be accepted as a valid reference product in this generic application. The applicant claimed a waiver from the requirement to provide *in vivo* bioequivalence data based on compliance with conditions set out in section 7.1a of the CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products (relating to products that are to be administered solely as an aqueous intravenous solution containing the same active substance as the currently approved product). This waiver was accepted.
As bioequivalence with a reference VMP has been demonstrated, results of safety tests are not required.

III.A Safety Tests
Pharmacological Studies
No pharmacodynamic or pharmacokinetic data were presented. Given the legal basis of this application, and accepted bioequivalence with the reference product, omission of these data was accepted.

Toxicological Studies
No toxicological study data were presented. Given the legal basis of this application, and accepted bioequivalence with the reference product, omission of these data was accepted.

User Safety
The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that the main risks identified are hypersensitivity reactions following exposure.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

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 be used to treat a small number of animals in a herd.

III.B Residues Documentation
Residue tests

No residue depletion studies were conducted because bioequivalence with the reference product is claimed, and it is assumed that residue depletion from edible tissues (muscle, fat, liver and kidney) will be comparable for both products.

Maximum Residue Limits
Benzylpenicillin is listed in Table I of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provision
Benzylpenicillin	Benzylpenicillin	All food producing species	50 50 50 50 4	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish. For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which eggs are produced for human consumption.

Withdrawal Periods
Based on the data provided above, a withdrawal period of 13 days for meat and offal in horses and 72 hours for milk are justified.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies
As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP has been demonstrated, pre-clinical studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

Development of resistance **and related risks in animals**
As this is a generic application, and the product is administered to the same target species for the same indications at the same posology using the same route of administration, the potential for resistance development is expected to be equivalent to that of the reference product.
Adequate warnings and precautions appear on the product literature.

Tolerance in the Target Species of Animals
No target animal tolerance studies in the target species were conducted.

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

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

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.