SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 300 mg/ml powder for solution for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each powder vial contains:
Active substance:
Benzylpenicillin sodium 6.36 g

Each ml of the reconstituted product contains:
Active substance:
Benzylpenicillin sodium 300 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
None	-

White or almost crystalline white.

3. CLINICAL INFORMATION

3.1 Target species

Horse.

3.2 Indications for use for each target species

Infections caused by micro-organisms sensitive to benzylpenicillin in horse.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use this product in the treatment of diseases caused by beta-lactamase-producing staphylococci.

3.4 Special warnings

Penicillins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross

reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This medicinal product must not be administered intramuscularly to horses because it causes local irritation.

Use of the product should be based on susceptibility testing of bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Due to the likely variability in susceptibility of bacteria to benzylpenicillin sodium, bacteriological sampling and susceptibility testing are recommended.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other penicillins and cephalosporins due to the potential for cross-resistance.

The usual aseptic precautions should be followed when administered the product.

Not for intrathecal administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
Avoid skin contact with this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure.

If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.
This product may cause eye irritation.
Avoid contact with the eyes.
In the event of accidental eye contact, rinse the affected eye(s) with plenty of clean water.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse reactions (frequency and seriousness)

Horse:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Digestive tract disorders Hypersensitivity reactions (urticaria, fever, oedema) Anaphylactic reactions

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Bactericidal effect of penicillin is prevented if bacteriostatic agents, like erythromycin or tetracyclines, are used concomitantly.

3.9 Administration routes and dosage

To prepare a ready-to-use solution, mix 17 ml of water for injection with 6.36 g benzylpenicillin sodium. This provides 21 ml of solution for injection with the concentration of 300 mg/ml. Sterile water is not included in the package, but any water for injection normally used in veterinary practice can be utilised as a solvent. Inject the solvent into the vial using a sterile needle of appropriate size. Shake the vial to mix the powder with water. Once the solution turns clear, it is ready for use.

10-20 mg/kg body weight intravenously (slowly), equivalent of
3.3 – 6.7 ml/100 kg body weight, 2 times a day. The treatment should last a minimum of 4 days.

To ensure the correct dosage, bodyweight should be determined as accurately as possible to avoid underdosing.

The reconstituted solution is a clear, colourless liquid.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In general, benzylpenicillin has a wide margin of safety and negative effects occur very seldom.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Not authorised for use in horses intended for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC Vet Code: QJ01CE01

(**Pharmacotherapeutic group:** beta-lactamase sensitive penicillins).

4.2 Pharmacodynamics

The active substance is benzylpenicillin. Penicillin has a bactericidal effect by interfering with the cell-wall synthesis and the effect is time-dependent. Benzylpenicillin is active against gram-positive aerobic and anaerobic bacteria as well as certain gram-negative bacteria, such as *Pasteurella, Fusobacterium* and *Haemophilus* species.

Beta-lactamase-producing staphylococci are resistant. Betahaemolytic streptococci are usually sensitive. Bacteria with the MIC value ≤ 0.5 µg/ml are sensitive, those with MIC 1 µg/ml have intermediate sensitivity and those with MIC ≥ 2 µg/ml are resistant.

4.3 Pharmacokinetics

Half-time of benzylpenicillin is < 1 hour in horses. Penicillin is widely distributed into extracellular fluid. Penicillin crosses biological membranes to a limited extent; however, its penetration increases in connection with inflammation, i.e. penetration into the CNS and udders increases in connection with meningitis and mastitis. Benzylpenicillin is excreted via the kidneys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Penicillin is inactivated by oxidizing and reducing agents, alcohol, glycol, acids, alkalis and high temperature. In addition to these, penicillin may be inactivated by the presence of zinc, copper, chromium, manganese and special iron ions in solution.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 24 hours.

5.3 Special precautions for storage

Powder:
This veterinary medicinal product does not require any special storage conditions.

Reconstituted product:
Store the reconstituted product in a refrigerator (2 – 8°C).

5.4 Nature and composition of immediate packaging

Colourlesstype II glass vials (50 ml) closed with bromobutyl rubber stoppers and aluminium seal and flip-off cap.

Pack sizes:

Cardboard box with 10 vials

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6 NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

7. MARKETING AUTHORISATION NUMBER

Vm 06043/4008

8. DATE OF FIRST AUTHORISATION

18 January 2022

9. DATE OF LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 22 May 2026