SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 6.36 g powder for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains:

Active substance:
Benzylpenicillin sodium 6.36 g (equivalent to 5.97 g benzylpenicillin).

After reconstitution with 17 ml of water for injections, each ml contains 303 mg of benzylpenicillin sodium (equivalent to 284 mg benzylpenicillin).

Powder vial: white or almost white crystalline powder.

Reconstituted solution for injection: clear, colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Treatment of infections caused by micro-organisms susceptible to benzylpenicillin.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.
Do not use this product in the treatment of diseases caused by beta-lactamase-producing staphylococci.
Do not use intramuscularly.

3.4 Special warnings

Cross-resistance has been shown between penicillin and other beta-lactam antibiotics. Use of the product should be carefully considered when susceptibility testing has shown resistance to beta-lactams because its effectiveness may be reduced.

After absorption, benzylpenicillin poorly penetrates biological membranes (e.g. blood-brain barrier) since it is ionised and poorly lipid soluble. Use of the product for treatment of meningitis or CNS infections may not be efficacious. Furthermore, benzylpenicillin penetrates mammalian cells poorly, hence this product may have little effect in treating intracellular pathogens.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information

and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the product should be in accordance with official, national and regional antimicrobial policies.

Unintentional extra-vasal administration may cause local irritation.

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

Beta-lactam antibiotics (penicillins, cephalosporins) can cause hypersensitivity (allergy) when injected, inhaled, ingested or in contact with skin. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity to beta-lactams should avoid contact with the veterinary medicinal product.

Handle this veterinary medicinal product with great care to avoid exposure. It is recommended to wear gloves.

In case of splashes in the eyes, rinse the eyes immediately with large quantities of water. In case of spillage onto skin, wash immediately with soap and water.

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.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Undetermined frequency (cannot be estimated from the available data):	Digestive tract disorders Hypersensitivity reaction[1] Anaphylaxis

[1] allergic

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 and lactation:

Can be used during pregnancy and 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. The effect of aminoglycosides may be enhanced by penicillins. The excretion of benzylpenicillin is delayed by phenylbutazone and acetylsalicylic acid.

3.9 Administration routes and dosage

Intravenous use.

To prepare a ready-to-use solution, mix 17 ml of water for injections with 6.36 g benzylpenicillin sodium. This provides 21 ml of solution for injection with the concentration of 303 mg benzylpenicillin sodium/ml. Sterile water is not included in the package, but any water for injections normally used in veterinary practice can be utilised as a solvent. Reconstitution should be performed under aseptic conditions. 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 benzylpenicillin sodium/kg body weight (equivalent to 9–18 mg benzylpenicillin/kg body weight) intravenously (slowly), equivalent of 3.3−6.6 ml/100 kg body weight, 2 times a day. The treatment duration is 4–5 days.

For infections requiring a treatment duration longer than 5 days, alternative therapy should be considered. The appropriate treatment duration should be chosen based on the clinical needs and individual recovery of the treated animal. Consideration should be given to the accessibility of the target tissue and characteristics of the target pathogen.

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

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

Symptoms of toxic effects are seen in the form of anxiety, urination and salivation.

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

Meat and offal: 13 days.
Milk: 72 hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QJ01CE01

4.2 Pharmacodynamics

The active substance is benzylpenicillin. Penicillin has a bactericidal activity 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.

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

Enterobacterales, *Bacteroides fragilis*, most *Campylobacter* spp., *Nocardia* spp. and *Pseudomonas* spp. as well as beta-lactamase–producing *Staphylococcus* spp. are resistant.

Resistance to benzylpenicillin in gram-positive bacteria is mainly due to the production of beta-lactamase enzymes that cleave the beta-lactam ring and thus inactivate benzylpenicillin. The resistance can be acquired also through reduced affinity of benzylpenicillin to penicillin-binding proteins (PBPs).

4.3 Pharmacokinetics

In horses, a maximum serum concentration of 52.4 mcg/ml was measured 5 minutes after intravenous administration of 10 mg/kg body weight. Serum concentration above 0.1 mcg/ml persisted for approximately 4 hours. After administration of 20 mg/kg body weight the corresponding concentration was 131.3 mcg/ml at approximately 6 hours. Half-life is approximately 1.5 hours.

Penetration into the CNS increases in connection with meningitis.

Benzylpenicillin is excreted unchanged 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 (store in a refrigerator 2°C–8°C).

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°C–8°C).

5.4 Nature and composition of immediate packaging

Colourless type 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 products 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(S)

VPA10664/009/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).