SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 300 mg/ml powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Powder vial contains:
Active substance:
Benzylpenicillin sodium 24 g

Solvent vial contains 64 ml of sterile water

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

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection
Powder vial: white or almost white crystalline powder
Solvent vial: clear, colourless liquid
Reconstituted solution for injection: clear, colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Horse.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in known 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.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i) Special precautions for use in animals

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.

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

Not for intrathecal administration.

ii) Special precautions for 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.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Allergic hypersensitivity reactions and gastrointestinal disorders can occur.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

4.8 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.

4.9 Amounts to be administered and administration route

To prepare a ready-to-use solution, mix 64 ml of sterile water with 24 g benzylpenicillin sodium. This provides 80 ml of solution for injection with the concentration of 300 mg/ml.

The package contains a transfer needle. Instructions for use for the transfer needle:

1. Remove one of the two protective caps of the transfer needle and pierce the water vial with the needle.
2. Remove the remaining protective cap of the transfer needle and pierce the powder vial from above with it.
3. Turn the vials upside down and let all water flow into the powder vial, then remove the transfer needle and the empty water vial.
4. Shake the powder 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Not authorised for use in horses intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: beta-lactamase sensitive penicillins.

ATC Vet Code: QJ01CE01.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 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.

6.3 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).

6.4 Special precautions for storage

Powder and Solvent: Store below 25°C in the outer carton. Protect from light.

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

6.5 Nature and composition of immediate packaging

Powder:
Colourless, glass vials (100 ml) (type II) glass vials closed with rubber stoppers (chlorobutyl) and aluminium seal and flip-off cap.

Solvent:
Colourless, glass vials (100 ml) (type I), closed with rubber stoppers (chlorobutyl) and aluminium seal and flip-off cap.

Polystyrene transfer needle

Pack sizes:
Cardboard box with 1 pair of vials (powder and solvent) and transfer needle
Cardboard box with 10 pairs of vials (powder and solvent) and transfer needles
Cardboard box with 40 (4 x 10) pairs of vials (powder and solvent) and transfer needles

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

8. MARKETING AUTHORISATION NUMBER

Vm 06043/4007

9. DATE OF FIRST AUTHORISATION

21 October 2020

10. DATE OF REVISION OF THE TEXT

October 2020

Approved 21 October 2020