

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each powder vial contains:

**Active substance:**

Benzylpenicillin sodium 24 g

Each solvent vial contains:

Water for injection 64 ml

Each ml of the reconstituted product contains:

**Active substance:**

Benzylpenicillin sodium 300 mg

**Excipients:**

| <b>Qualitative composition of excipients and other constituents</b> | <b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b> |
|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Water for injections                                                |                                                                                                                                |

Powder vial: white or almost white crystalline powder

Solvent vial: clear, colourless liquid

### **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.

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 events

Horse:

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

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 ATCvet Code: QJ01CE01.**

### **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  $\leq 0.5 \mu\text{g/ml}$  are sensitive, those with MIC  $1 \mu\text{g/ml}$  have intermediate sensitivity and those with MIC  $\geq 2 \mu\text{g/ml}$  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 and solvent:

Store below 25°C. Keep the vials in the outer carton in order to protect from light.

Reconstituted product:

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

### **5.4 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.

### **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 06043/4007

**8. DATE OF FIRST AUTHORISATION**

21 October 2020

**9. DATE OF THE LAST REVISION OF THE 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](http://www.gov.uk)

*Gavin Hall*

Approved: 22 May 2026