PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX, 10 x l vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 300 mg/ml powder for solution for injection
benzylpenicillin sodium

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Benzylpenicillin sodium 6.36 g

3. PHARMACEUTICAL FORM

Powder for solution for injection

4. PACKAGE SIZE

10 x 6.36 g

5. TARGET SPECIES

Horse

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horse: i.v.

Read the package leaflet before use.

Only for use by veterinary surgeons.

Mix 17 ml of water for injection with 6.36 g benzylpenicillin sodium to get 21 ml of solution for injection with the concentration of 300 mg/ml. Sterile water it is not included in the package, but any water for injestion 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.

8. WITHDRAWAL PERIOD

Withdrawal period: Not authorised for use in horses intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full warnings.

10. EXPIRY DATE

Shelf life after reconstitution according to directions: 24 hours

EXP:
Once solution is prepared use by:

11. SPECIAL STORAGE CONDITIONS

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

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Distributed by
Nimrod Veterinary Products Ltd
2, Wychwood Court, Cotswold Business Village
Moreton-in-Marsh
GL54 0JQ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06043/4008

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINUMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 300 mg/ml powder for solution for injection

benzylpenicillin sodium

2. QUANTITY OF THE ACTIVE SUBSTANCE

6.36 g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6.36 g

4. ROUTE OF ADMINISTRATION(S)

Horse: i.v.

Reconstitution: see the carton and package leaflet

5. WITHDRAWAL PERIOD

Withdrawal period: Not authorised for use in horses intended for human consumption.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

POM-V

PACKAGE LEAFLET FOR:
Geepenil vet 300 mg/ml powder and solvent for solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 300 mg/ml powder for solution for injection
benzylpenicillin sodium

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Powder vial contains:
Active substance:
Benzylpenicillin sodium 6.36 g

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

Powder vial: white or almost white crystalline powder

Reconstituted solution for injection: clear, colourless liquid

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance.

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

6. ADVERSE REACTIONS

Allergic hypersensitivity reactions and gastrointestinal disorders can occur.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Horse: 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.

9. ADVICE ON CORRECT ADMINISTRATION

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 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. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

In-use shelf life after reconstitution according to directions:
24 hours (store in a refrigerator 2°C – 8°C).

When the ready-to-use solution has been prepared, using the in-use shelf-life which is specified on this package leaflet (see above), the date and time on which the

ready-to-use solution should be discarded should be determined. This discard date and time should be written in the space provided.

12. SPECIAL WARNING(S)

For Animal Treatment Only

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.

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.

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.

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):
In general, benzylpenicillin has a wide margin of safety and negative effects occur very seldom.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused veterinary medicinal product, or waste materials, in accordance with local requirements (i.e. via household waste). Medicines should not be disposed of via wastewater.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

15. OTHER INFORMATION

LEGAL CATEGORY

POM-V

To be supplied only on veterinary prescription

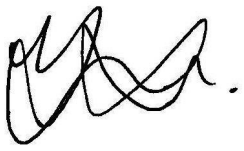
PACKAGE QUANTITIES

Pack sizes:
Cardboard box with 10 vials

MARKETING AUTHORISATION NUMBER

Vm 06043/4008

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder. Distributed by Nimrod Veterinary Products Ltd, 2, Wychwood Court, Cotswold Business Village, Moreton-in-Marsh, GL54 0JQ, United Kingdom.



Approved: 18 January 2022