PACKAGE LEAFLET

Geepenil vet 24 g 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

Marketing authorisation holder:
[To be completed nationally]

Manufacturer responsible for batch release:
[To be completed nationally]

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 24 g powder and solvent for solution for injection
benzylpenicillin sodium

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Active substance: One powder vial contains 24 g (40 million IU) benzylpenicillin sodium.

Excipient: One solvent vial contains 64 ml of water for injections.

4. INDICATIONS

Infections caused by micro-organisms sensitive to benzylpenicillin in cattle, pig and horse.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance.

6. ADVERSE REACTIONS

Allergic hypersensitivity reactions (urticaria, fever and edema), anaphylactic 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

Cattle, pig and horse.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Cattle: 2–3 ml/100 kg (6–9 mg/kg) 2 times a day minimum for 3 days.
Pig: 0.2 ml/10 kg (6 mg/kg) 2 times a day minimum for 3 days.
Horse: 3.2–6.4 ml/100 kg (9.5–19 mg/kg) 2 times a day minimum for 4 days.

Cattle: Intramuscularly (IM) or slowly intravenously (IV).
Pig: Intramuscularly (IM).
Horse: Slowly intravenously (IV).

9. ADVICE ON CORRECT ADMINISTRATION

To prepare a ready-to-use solution, transfer the whole amount of sterile water (64 ml) into the dry powder vial by using the transfer needle. Shake well. 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 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. WITHDRAWAL PERIODS

Meat and offal: 10 days.
Milk: 2 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf life after reconstitution according to directions: 24 hours (store below 25 °C) or 5 days (store in a refrigerator (2 °C – 8 °C), do not freeze).

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.

12. SPECIAL WARNINGS

Special warnings for each target species:
None.

Special precautions for use in animals:
This medicinal product must not be administered intramuscularly to horses because it causes 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.

Do not handle this product if you know you are sensitised to beta-lactams or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

In case of splashes in the eyes, rinse the eyes immediately with large quantities of water. In case of contact with the skin, wash immediately with soap and water. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

If you experience symptoms following exposure such as skin irritation, you should seek medical advice and show the physician this warning. Swelling of the face, eyes, lips or larynx or difficulty with breathing, are more serious symptoms and require immediate medical care.

Wash hands after use.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions are expected in the event of overdose.

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

2020-11-12

15. OTHER INFORMATION

Combination pack containing one glass vial with powder and one glass vial with water for injections. The pack also contains a transfer needle.

Pack sizes: 24 g: 1 x (I + II), 10 x 1 x (I + II), 4 x 10 x 1 x (I + II)

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.