SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Geepenil vet 24 g powder and solvent for solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.
Powder for solution for injection: white or almost white crystalline powder.
Solvent: clear colorless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pig and horse.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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

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.

4.6 Adverse reactions (frequency and seriousness)

Allergic hypersensitivity reactions (urticaria, fever and edema), anaphylactic reactions and gastrointestinal disorders can occur.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Cattle: Intramuscularly (IM) or slowly intravenously (IV) 2–3 ml/100 kg (6–9 mg/kg) 2 times a day minimum for 3 days.

Pig: Intramuscularly (IM) 0.2 ml/10 kg (6 mg/kg) 2 times a day minimum for 3 days.

Horse: Slowly intravenously (IV) 3.2–6.4 ml/100 kg (9.5–19 mg/kg) 2 times a day minimum for 4 days.

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.

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

No adverse reactions are expected in the event of overdose.

4.11 Withdrawal periods

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, beta-lactamase sensitive penicillins.
ATCvet code: QJ01CE01.

5.1 Pharmacodynamic properties

The active substance of Geepenil vet is benzylpenicillin. Penicillin has a bactericidal effect by interfering with the cell-wall synthesis. 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 and mastitis-inducing *Streptococcus agalactiae, dysgalactiae* and *uberis* are usually sensitive. Bacteria with the MIC value < 0.12 microg/ml are sensitive, those with MIC 0.25–2 microg/ml have intermediate sensitivity and those with MIC > 2 microg/ml are resistant.

5.2 Pharmacokinetic particulars

Benzylpenicillin in solution is rapidly absorbed. At recommended doses, the maximum serum concentration of 5 microg/ml is achieved in cattle after about 30 minutes and the maximum serum concentration of 13 microg/ml in pigs after 15 minutes. Half-time of benzylpenicillin is about 1.5 hours in cattle and < 1 hour in pigs and horses. Following absorption, 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 Major 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.

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 below 25 °C) or 5 days (store in a refrigerator (2 °C – 8 °C), do not freeze).

6.4 Special precautions for storage

For storage conditions after reconstitution of the medicinal product, see section 6.3.
This veterinary medicinal product does not require any special storage conditions. Do not freeze.

6.5 Nature and composition of immediate packaging

Combination pack:
I: 24 g of powder for solution for injection in a colorless 100 ml glass vial with a rubber stopper.
II: 64 ml of water for injections in a colorless 100 ml glass vial with a rubber stopper.
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.

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

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2020-11-12

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.