B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Geepenil vet 24 g powder and solvent for solution for injection

2. Composition

One vial with powder contains:

Active substance: 24 g (40 million IU) benzylpenicillin sodium.

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

Powder: white or almost white crystalline powder.
Solvent: clear colorless liquid.

3. Target species

Cattle, pig and horse.

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:
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.

People with known hypersensitivity to beta-lactams should avoid contact with the veterinary medicinal product.

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 spillage onto 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:
No adverse reactions are expected in the event of overdose.

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.

7. Adverse events

Cattle, pig and horse:

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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 (i.m.) or slowly intravenously (i.v.).
Pig: Intramuscularly (i.m.).
Horse: Slowly intravenously (i.v.).

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.

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.

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).

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number: [To be completed nationally]

Combination pack including:
Powder: Colorless glass vial of 100 ml with a chlorobutyl rubber stopper.

Solvent: Colorless glass vial of 100 ml with a chlorobutyl rubber stopper.

The pack also contains a transfer needle.

Pack sizes:
Single pack containing 1 vial with 24 g powder and 1 vial with 64 ml solvent.
Multipack containing 10 individually packed vials with 24 g powder each and 10 vials with 64 ml solvent each.
Multipack containing 40 individually packed vials with 24 g powder each and 40 vials with 64 ml solvent each.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

25/03/2025

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Orion Corporation
Orionintie 1
02200 Espoo
Finland

Manufacturer responsible for batch release:
Orion Corporation Orion Pharma
Orionintie 1
02200 Espoo
Finland

Local representatives and contact details to report suspected adverse events:

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

[To be completed nationally]