ANNEX I

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

One powder vial contains:

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

Excipient:

Qualitative composition of excipients and other constituents
Water for injections

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pig and horse.

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

None.

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 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.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 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

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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

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

Horse: Slowly intravenously (i.v.) 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions are expected in the event of overdose.

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

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01CE01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 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.

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

5.3 Special precautions for storage

Do not freeze.

For storage conditions after reconstitution of the medicinal product, see section 5.2.

5.4 Nature and composition of immediate packaging

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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(S)

[To be completed nationally]

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

25/03/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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