

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PEN/STREP Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Procaine Benzylpenicillin	200 mg
Dihydrostreptomycin Sulphate	
equivalent to Dihydrostreptomycin	200 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Methyl, ethyl and propyl parahydroxybenzoate as sodium salts (as preservative)	1.5 mg
Sodium formaldehyde sulfoxylate (as antioxidant)	1.25 mg
Disodium edetate	
Povidone K12	
Polysorbate 80	
Sodium citrate	
Lecithin	
Procaine hydrochloride	
Cetrimide	
Potassium chloride	
Water for injections	

A white to off-white suspension for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, and pigs.

3.2 Indications for use for each target species

For the treatment of systemic infections caused by or associated with organisms sensitive to penicillin and/or streptomycin including:

Corynebacterium pyogenes
Erysipelothrix rhusiopathiae
Klebsiella pneumoniae
Listeria spp.

Pasteurella haemolytica
Pasteurella multocida
Staphylococcus spp. (non-penicillinase producing)
Streptococcus spp.

The veterinary medicinal product will therefore be effective in the treatment of infections caused by susceptible organisms including: erysipelas; navel/joint ill; respiratory tract infections, including pneumonia and atrophic rhinitis; listeriosis, meningitis; septicaemia; toxæmia associated with mastitis; urogenital tract infections; enteritis and secondary bacterial invaders in diseases of primary viral origin.

3.3 Contraindications

Not for intravenous administration.

Do not use in sheep producing milk for human consumption.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in target species:

Administer by deep intramuscular injection only.

Special precautions to be taken by the person administering the medicinal product to animals:

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

1. People with known hypersensitivity to penicillin and cephalosporins should avoid contact with the veterinary medicinal product.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, sheep, pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction ¹ , Anaphylaxis ¹
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¹Sometimes fatal.

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Vomiting ¹ ; Pyrexia ^{1,3} , Listless ¹ ; Shivering ¹ , Incoordination ¹ ; Vaginal discharge ²
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¹ In suckling and fattening pigs.

² In pregnant sows and gilts, which could be associated with abortion.

³ Transient.

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 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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interactions

None known.

3.9 Administration routes and dosage

Deep Intramuscular use.

Shake well before use.

The stopper should not be punctured more than 25 times.

Recommended dosage rate is as follows: 8 mg/kg bodyweight procaine penicillin and 10 mg/kg bodyweight dihydrostreptomycin sulphate achieved by administering 1 ml per 25 kg bodyweight. The dose should be given once daily for up to 3 consecutive days.

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

Not applicable.

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

Milk for human consumption must not be taken during treatment.

Animals must not be slaughtered for human consumption during treatment.

Cattle:

Milk: 48 hours.

Meat and offal: 21 days.

Sheep:

Meat and offal: 28 days.

Not authorised for use in ewes producing milk for human consumption.

Pigs:

Meat and offal: 18 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code: QJ01RA01

4.2 Pharmacodynamics

Procaine penicillin is administered by deep intramuscular injection to create a depot from which benzylpenicillin is slowly liberated. It exerts its effect on multiplying bacteria by interfering with the formation of the cell wall.

Dihydrostreptomycin is an aminoglycoside antibiotic which after penetration of the cell envelope binds to receptors on the 30s subunit of the ribosome. It induces misreading of the genetic code on the messenger ribonucleic acid (mRNA) template.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Multidose 50 ml and 100 ml uncoloured Type II (Ph. Eur.) glass vial and 50 ml, 100 ml and 250 ml plastic (PET) vials, sealed with a bromobutyl rubber stopper and aluminium cap, in outer cartons of one vial.

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

Chem-Pharm Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10823/002/001

8. DATE OF FIRST AUTHORISATION

01/10/1997

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

19/11/2024

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).