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	
Methyl, ethyl and propyl parahydroxybenzoates as sodium salts (as preservative)	1.5 mg
Sodium Formaldehyde Sulfoxylate (as antioxidant)	1.25 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
A white to off-white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, Sheep, Pigs

4.2 Indications for use, specifying the 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.

PEN/STREP 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; toxaemia associated with mastitis; urogenital tract infections; enteritis and the control of secondary bacterial invaders in diseases of primary viral origin.

4.3 Contraindications

Not for intravenous administration.
Not for use in sheep producing milk for human consumption.
Contra-indicated in known cases of hypersensitivity to penicillins.

4.4 Special Warnings for each target species

Occasionally in sucking and fattening pigs, administration of PEN/STREP may cause transient pyrexia, vomiting, shivering, listlessness and incoordination.

4.5 Special precautions for use

Special precautions for use in animals

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

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.

4.6 Adverse reactions (frequency and seriousness)

Hypersensitivity reactions, including anaphylaxis (sometimes fatal), have been reported rarely.

4.7 Use during pregnancy, lactation or lay

PEN/STREP can be safely administered to pregnant and lactating animals. However, in pregnant sows and gilts a vulval discharge which could be associated with abortion has been reported.

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

Shake well before use.
Administer by deep intramuscular injection.
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.

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

Not applicable.

4.11 Withdrawal period(s)

Milk for human consumption must not be taken during treatment.
Milk for human consumption may only be taken after 48 hours from the last treatment.
Animals must not be slaughtered for human consumption during treatment.
Cattle intended for human consumption should not be slaughtered until 21 days after the last treatment.
Sheep intended for human consumption should not be slaughtered until 28 days after the last treatment.
Pigs intended for human consumption should not be slaughtered until 18 days after the last treatment.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antibacterial
ATCvet Code: QJ01RA01

5.1 Pharmacodynamic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate
Sodium ethyl parahydroxybenzoate
Sodium propyl parahydroxybenzoate
Sodium formaldehyde sulphoxylate
Disodium edetate
Povidone K12
Polysorbate 80
Sodium citrate
Lecithin
Procaine hydrochloride
Cetrimide
Potassium chloride
Citric acid anhydrous
Water for injections

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

Store between 2°C and 8°C.
Keep vial in the outer carton in order to protect from light.

6.5 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, containing a white to off-white sterile suspension.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7. MARKETING AUTHORISATION HOLDER

Chem-Pharm Limited

8. MARKETING AUTHORISATION NUMBER(S)

VPA10823/002/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/10/1997

10. DATE OF REVISION OF THE TEXT

02/03/2024