SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pen & Strep Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Procaine Penicillin	200 mg
Dihydrostreptomycin Sulphate	250 mg

Excipients

The product also contains 1.5mg Hydroxybenzoate Esters (as Nipasept Sodium) as antimicrobial preservative and 1.25mg sodium formaldehyde sulphoxylate dihydrate as antioxidant.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for Injection
A white to off-white aqueous suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
Horses
Sheep
Pigs

4.2 Indications for use, specifying the target species

For the treatment of systemic infections in cattle, horses, sheep and pigs caused by or associated with organisms sensitive to penicillin and/or streptomycin including:

Arcanobacterium pyogenes
Erysipelothrix rhusiopathiae
Klebsiella pneumoniae
Listeria spp
Mannheimia haemolytica
Pasteurella multocida
Staphylococcus spp (non-penicillinase producing)

Streptococcus spp
Salmonella spp

4.3 Contraindications

Contraindicated in known cases of hypersensitivity to penicillins.

4.4 Special Warnings for Each Target Species

Use with care in animals known to have kidney disease or defective renal function.
Do not exceed the recommended dosage or duration of treatment.

4.5 Special Precautions for Use

i. Special precautions for use in animals:

Care should be taken not to exceed the recommended dosage. Aminoglycosides have a narrower margin of safety than beta lactam antibiotics.

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

Care should be taken to avoid accidental self-injection. In the case of accidental self-injection, seek medical advice immediately.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions 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 or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

   Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, hypersensitivity reactions can occur and very rarely, these can be fatal. Very rarely, in sucking and fattening pigs, administration may cause a transient pyrexia, vomiting, shivering, listlessness and incoordination. A palpable but transient local reaction may occur at the site of intramuscular administration in horses.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

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 Interactions with other medicinal products and other forms of interaction

Do not administer with other antibiotics such as tetracyclines or with other aminoglycosides.

4.9 Amount to be administered and administration route

Shake the vial before use.
Administer by deep intramuscular injection.
Recommended dosage rate is 8 mg/kg bodyweight procaine penicillin with 10 mg/kg bodyweight dihydrostreptomycin sulphate equivalent to 1 ml per 25 kg bodyweight. Treatment should be given once daily for up to 3 consecutive days.
The maximum dose volume administered at one site should not exceed 15 ml for horses, 6 ml for cattle, 3 ml for sheep and 1.5 ml for pigs.

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

No treatment specified.

4.11 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment.

Sheep:
Not to be used in sheep producing milk for human consumption.
Sheep intended for human consumption should not be slaughtered until 14 days after the last treatment.

Cattle:
Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cows after 48 hours from the last treatment.
Cattle intended for human consumption should not be slaughtered until 14 days after the last treatment.

Pigs:
Pigs intended for human consumption should not be slaughtered until 14 days after the last treatment.

Horses:
Not to be used in horses intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Antibacterials for systemic use, combinations of antibacterials, penicillins, combinations with other antibacterials.

ATCvet Code: QJ01RA01

5.1 Pharmacodynamic properties

Penicillin G is a beta-lactam antibiotic and its structure contains the beta- lactam ring and thiazolidine ring common to all penicillins. Beta-lactam antibiotics prevent the bacterial cell wall of susceptible Gram-positive bacteria from forming by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidase enzymes, which catalyse cross- linkage of the glycopeptide polymer units that form the cell wall. They exert a bactericidal action but cause lysis only of growing cells.

Dihydrostreptomycin is an aminoglycoside antibiotic active against gram-negative aerobes, which after penetration of the cell envelope binds to receptors on the 30S sub unit of the bacterial ribosome. It induces misreading of the genetic code on the messenger ribonucleic acid (mRNA) template, causing bacteriostasis. Aminoglycosides exert synergistic action in combination with beta-lactam antibiotics.

5.2 Pharmacokinetic properties

After injection of Pen & Strep, the procaine penicillin is rapidly absorbed from

the site of injection, with maximum penicillin levels of between 1 and 2 µg/ml for horses, sheep and pigs and 0.5 µg/ml for cattle, being obtained within 2 hours of injection.

The penicillin elimination half-lives are approximately 2 hours for sheep and pigs, 5 hours for cattle and 11 hours for horses. Dihydrostreptomycin is absorbed at a similar rate, with maximum plasma levels of 23 µg/ml being obtained for cattle, sheep and pigs, and 15 µg/ml for horses. The elimination half-lives are approximately 2 hours for cattle, sheep and pigs and 4 hours for horses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinylpyrrolidone
Polysorbate 80
Lecithin
Sodium Citrate
Disodium Edetate
Procaine Hydrochloride
Sodium Formaldehyde Sulphoxylate
Nipasept (as sodium salt) composed of:
Methyl-P-Hydroxybenzoate,
Propyl-P-Hydroxybenzoate,
Ethyl-P-Hydroxybenzoate
Citric Acid
Potassium Chloride
Water for Injection

6.2 Major Incompatibilities

None Known.

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store between 2 – 8^{o}C.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Clear type II glass vials of 100 ml sealed with bromobutyl rubber bungs and aluminium caps.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MANUFACTURER

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Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

8. MARKETING AUTHORISATION HOLDER

Comex Ltd.
Nablus Road No. 1
P.O.B. 19943, Jerusalem 97200

9. MARKETING AUTHORISATION NUMBER

081-64-92222-00

Revised in April 2023 according to MoH's guidelines.