NEO STREP-PEN INJECTION

(Streptomycin Sulphate, Procaine Penicillin)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NEO STREP-PEN INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Vial Contains:
Streptomycin Sulphate…….....…….160 mg
Procaine Penicillin……..200 mg

3. PHARMACEUTICAL FORM

Injectable Suspension

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Buffaloes, Camel & Goat.

4.2. Indications for use specifying the target species

Treatment of local and systemic infections caused by bacteria sensitive to penicillin or dihydrostreptomycin in Cattle, Sheep, Goats & Camels.
Penicillin has been shown in vitro to be effective against aerobic Gram-positive bacteria such as Staphylococcus aureus, streptococci, most Actinomycetes (Corynebacteria), and Erysipelothrix spp.
The Gram-positive anaerobic bacteria that are sensitive include most Clostridia.
Penicillin has been shown to be effective in vitro against some Gram-negative bacteria, including Pasteurella multocida and Actinobacillus (Haemophilus) pleuropneumoniae.
Dihydrostreptomycin has been shown to be effective in vitro against Gram-negative bacteria such as E.coli, Pasteurella spp., Salmonella spp., and Klebsiella spp., as well as against some Gram-positive bacteria and Leptospira.
The synergism of the penicillin-streptomycin combination results in greater activity compared to the use of either antibiotic alone

4.3. Contraindications

Do not use in case of hypersensitivity to the active ingredients or to any of the excipients.
Do not administer to rabbits and small rodents.
Do not administer to individuals with renal insufficiency, as nephrotoxicity and neurotoxicity may occur.
Do not administer intravenously.

4.4. Special precautions for use

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Whenever possible the product should only be used on the basis on susceptibility testing

Special precautions to be taken by the person administering the 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 can occasionally be serious.

People with known hypersensitivity to the active substances should avoid contact with the veterinary medicinal product.
Avoid contact with eyes, skin, and mucous membranes.
Wash hands thoroughly after handling the product.
Keep out of reach of children.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label.

4.5. Adverse reactions (frequency and seriousness)

Occasional allergies to penicillins have been observed but these are very rare. Hypersensitivity (allergic) reactions to penicillins can vary from localised swelling to anaphylaxis and death.
Procaine penicillin G can, under certain circumstances, be toxic and even lethal to Ruminants and this is thought to be due to a sudden release of toxic amounts of free procaine. The symptoms include shivering, lassitude, inappetence, vomiting, cyanosis of the extremities and pronounced pyrexia (40°C and over). A vulval discharge may appear and some animals may abort. Alarming side-effects are most likely to occur when Ruminants with erysipelas are injected with an older and/or, heat-affected procaine penicillin formulation. Treatment with 5 mg dexamethasone will result in rapid recovery.

4.6. Use during pregnancy and lactation or lay

The product can be used during pregnancy and breastfeeding. No toxic effects on the fetus or on the number of births have been observed after the administration of this Injection Both penicillin and streptomycin can appear in the milk of lactating animals, No side effects have been observed in the offspring

4.7. Interaction with other veterinary medicinal products and other forms of interaction

Tetracycline are bacteriostatic antibiotics that presumably may interfere with a bactericidal agent such as penicillin. Since penicillin act by inhibiting cell wall synthesis, agents such as tetracyclines, which inhibit protein synthesis, could mask the bactericidal effect of penicillin. If penicillin is used with a tetracycline, it would be prudent to observe the following points when possible:
1. Be sure that adequate amounts of each agent are given; antagonsim is most likely to occur when barely sufficient amounts of each agent are given.
2. Begin administration of the penicillin at least a few hours before the administration of tetracycline

4.8. Dosage and administration route

Shake well before use.
The recommended dose is 4 ml per 100 kg bodyweight i.e. 8 mg procaine penicillin and 10 mg dihydrostreptomycin sulphate per kg. The dose should be given once daily for up to 3 consecutive days. To ensure a correct dosage body weight should be determined as accurately as possible to avoid under-dosing.
For intramuscular administration only.

Species	Dose (ml)	kg Bodyweight
Cattle. Buffalo & Camel	4.0	100
Calf	2.0	50
Sheep & Goat	1.0	25
Lamb	0.4	10

Clean the area of injection and swab with spirit.
The maximum dose volume recommended at any one site for cattle is 20 ml.
Administer alternately on the left side and the right side.

4.09. Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the stated dose. Hypersensitivity (allergic) reactions to penicillins can vary from localised swelling to anaphylaxis and death. Therapy involves hot-or cold- water soaks and/or corticosteroids

4.10. With drawl period:

Cattle & Camel:
Meat and offal: 21 days
Milk: 72 hours
Sheep:
Meat and offal: 21 days
Milk: Not for use in lactating ewes producing milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Penicillins, Combinations with other Antibacterials.
ATCvet code: **QJ01RA01**

5.1. Pharmacodynamics properties

The active ingredients are penicillin (procaine) and Streptomycin.
Penicillin is a β-lactam antibiotic with a bactericidal action, as it interferes with the synthesis of the bacterial cell wall at the level of peptidoglycans, while streptomycin sulfate belongs to the group of aminoglycoside antibiotics and acts directly at the ribosomal level (30S subunit), causing the formation of abnormal bacterial peptide chains
The combination is active against both Gram-positive and Gram-negative bacteria.

Penicillin in vitro has been shown to be effective against aerobic Gram-positive bacteria such as Staphylococcus aureus, streptococci, most Actinomycetes (Corynebacteria), and Erysipelothrix spp. The sensitive Gram-positive anaerobic bacteria include most Clostridia. Penicillin has also been shown to be effective in vitro against some Gram-negative bacteria, including Pasteurella multocida and Actinobacillus (Haemophilus) pleuropneumoniae.

Streptomycin sulfate has been shown to be effective in vitro against Gram-negative bacteria such as E.coli, Pasteurella spp., Salmonella spp., and Klebsiella spp., as well as against some Gram-positive bacteria and Leptospira.

The combination of the two antibiotics, due to their different and synergistic mechanisms of action one inhibiting bacterial cell wall synthesis and the other inhibiting bacterial protein synthesis results in greater activity compared to the use of each antibiotic alone.

Among the pathogens found to be sensitive to benzylpenicillin, the following MICs were observed: Streptococcus pneumoniae with MIC90 levels of 0.03 mg/l; Streptococcus pyogenes with MIC90 levels ranging from 0.015 to 0.03 mg/l; Staphylococcus aureus with MIC90 of 0.5 mg/l; Clostridium perfringens with MIC90 levels of 0.5 mg/l..

5.2 Pharmacokinetic information

Benzylpenicillin procaine is gradually absorbed from the injection site. Therapeutic blood levels are maintained after intramuscular injection for 24-48 hours. In cattle, the Cmax was found to be 5.5 ± 2.6 μg/ml, the Tmax was 0.75 ± 0.27 hours, while the AUC(0-∞) was 10.8 ± 4.9 μg x h/ml.

The antibiotic distributes throughout all body tissues. The apparent volumes of distribution are relatively low (0.2–0.3 l/kg). The passage through biological membranes or across the blood-brain barrier and cerebrospinal barrier is favored by inflammation, allowing inhibitory concentrations of the drug to be reached in these normally inaccessible sites for penicillins. The mean half-life is 0.50 hours.

Penicillins are almost completely eliminated through the kidneys and are found in high concentrations in the urine.

Streptomycin sulfate is rapidly absorbed after intramuscular injection and reaches its peak plasma concentration approximately one hour after treatment. Excretion occurs mainly through urine. After intramuscular injection of a dose of 10 mg/kg body weight in cattle, the following parameters have been observed: Cmax of 44.3 ± 15.2 μg/ml, Tmax of 1.1 ± 0.4 hours, and AUC of 207.2 ± 33.8 mcg/(ml/h).

The combination of the two active ingredients maintains active plasma levels for at least 12 hours.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

Do not mix with other veterinary medicines.

6.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use immediately, do not store.

6.3. Special precautions for storage

Store below 30°C in a dark & dry place.
Do not freeze.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.4. Nature and composition of primary conditioning

Glass Vial of 10ml, 50 ml & 100 ml glass vial closed with bromobutyl rubber stopper and sealed with aluminium flip off seal.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 053997

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 31-03-2009

10. DATE OF REVISION OF THE TEXT

05-10-2024

MANUFACTURED BY:
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