PENBIOTIC INJECTION

(Benzyl Penicillin, Procaine Penicillin, Streptomycin Sulphate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Penbiotic Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Vial Contains:
Benzyl Penicillin ……...…500,000 IU
Procaine Penicillin ……..…….1,500,000 IU
Streptomycin Sulphate……..……5 gm

3. PHARMACEUTICAL FORM

Powder for suspension for injection

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Goats, Poultry, Camel and Horses.

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4.2. Indications for use specifying the target species

The product Penbiotic Injection is used in the treatment of infections caused by penicillin- and streptomycin-sensitive germs: pneumonia, bronchopneumonia, arthritis, phlegmon. Abscesses, septic conditions. dystocia, sapremia. Caesarean sections, omphalophlebitis, rubella in cattle, sheep, Goats, Poultry, Camel and Horses. The spectrum of activity is primarily manifested against Gram-positive and Gram-negative cocci, as well as Gram-positive bacilli.

4.3. Contraindications

Not to be used for infections caused by penicillin- and streptomycin-resistant germs. Not to be used for older animals, those with pre-existing renal or Otic diseases. Not recommended for the treatment of infections with a super acute course.
Not to be administered subcutaneously because it produces local inflammation and sometimes micro hemorrhages. Not to be used in case of known hypersensitivity to the active substances.

4.5. Special precautions for use

Special precautions for use in animals:

The product should be used based on antimicrobial susceptibility testing. If this is not possible. Treatment should be based on local epidemiological information.

National legislation on the use of antimicrobial substances should be taken into account.
Caution should be exercised in dogs with chronic nephritis.
In omnivores and carnivores, it is necessary to alkalize the urine.

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

People with known hypersensitivity to benzyl penicillin, streptomycin sulphate or procaine should avoid contact with the veterinary medicinal product.
In case of accidental self-injection. Seek medical advice immediately and show the package leaflet or the label to the physician.
Specific protective equipment should be worn when handling the veterinary medicinal product.

4.6. Adverse reactions (frequency and seriousness)

Uncommon: pain at the injection site (in the case of high doses).
Unknown frequency: allergic reactions, specific anaphylaxis, contact dermatitis, urticaria
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 a treatment) -Common (more than 1 but less than 10 animals in 100 animals)
-Uncommon (more than i 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)

4.7. Use during pregnancy and lactation or lay

Can be used during pregnancy.
Do not use during lactation.

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

Penicillins are antagonistic to chloramphenicol, cephalothin, erythromycin and tetracyclines, which have a mechanism of destruction of microorganisms based on blocking the formation of the bacterial cell wall during division.
The combination of penicillins with streptomycin is useful in the treatment of endocarditis, bacteremia, urinary infections due to enterococci.
Analgesic salicylates and some sulfonamides potentiate the effect of penicillins, in some cases.
Probenecid acts competitively with penicillins, prolonging their excretion through the renal tubules, leading to the maintenance of a high level of plasma concentration and prolonging the effect. The activity of streptomycin decreases in the presence of salts such as: ammonium acetate, sodium chloride, sodium sulfate, festats, potassium chloride, sodium tartrate, borax.
The activity of synuptomycin is inhibited in the presence of calcium salts, magnesium salts, hypophosphites, and ascorbic acid.
The combination of streptomycin with methicillin or carbenicillin in the syringe or infusion inactivates the antibiotic. Urea, cysteine, semicarbazide inactivate streptomycin. The product should not be combined with other aminocyclitol-aminoglycoside antibiotics (neomycin, kanamycin) because they increase the toxicity of streptomycin (damage to the VIII nerve, nephrotoxicity, occurrence of myasthenic syndrome, neuromuscular blockade of the curare type). The concomitant or immediate consecutive use of drugs that affect one of the above systems should be avoided (muscle relaxants, general anesthetics, drugs with pronounced nephrotoxicity). In the treatment with Propamycin, the combination of drugs that alkalize the urine is recommended, because streptomycin is more active in an

alkaline environment, and alkaline urine containing streptomycin is less irritating to the renal tissue.

4.9. Dosage and administration route

Inject intramuscularly only. Add 10ml water for Injection, 3ml per 50kg body weight.
Poultry: 0.25ml per 1 kg body weight
Sheep & Goat: 2ml per 25 kg body weight
Cattle & Buffaloes: 15 per 250kg body weight
Camel & Horses: 30ml per 500kg body weight
In infections with a superacute evolution, it is advisable to administer it simultaneously with a dose of penicillin with rapid absorption and distribution.
To ensure the correct dose, the body weight must be determined as accurately as possible, so as to avoid underdosing.

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

Phenomena of renal toxicity and neuromuscular blockade may occur in all species. In such cases, glucose serums are administered.

4.11. With drawl period:

Meat and offal: 28 days.
Milk: 7 days and

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, penicillins, combinations with other antibacterials.
ATC veterinary code: QI0TRA01

5.1. Pharmacodynamic properties

Benzylpenicillin is a natural penicillin obtained from a strain of Penicillium chrysogenum. Benzylpenicillin has bactericidal properties of a degenerative type. It binds to specific receptor proteins PBP (penicillin binding protein) located in the cytoplasmic membrane of bacteria. These receptor proteins (which include transpeptidases, carboxypeptidases and endopeptidases) are enzymes involved in the terminal stages of cell wall formation and in cell wall repair during cell growth and division. Benzylpenicillin binds to and inactivates specific receptor proteins, preventing bacterial wall formation.
Benzylpenicillin has a relatively narrow spectrum of activity. Gram-positive cocci (Streptococcus spp... Staphylococcus spp). Gram-negative (Miniserie spp.), Gram-positive bacilli (Ensipelorhiz rhusiopathia. Begillus anthracis. Clostridium spp.) are sensitive to the action of benzylpenicillin because they have specific and available membrane receptors. Also Actinomyces spp... Leptospira spp. 3unjensibile to the action of benzylpenicillin (in high doses).
It is not active against penicillinase-producing bacteria.
Benzylpenicillin is a crystalline salt of benzylpenicillin with procaime. It is an injectable penicillin with a delayed effect. The antimicrobial spectrum is that of benzylpenicillin (Penicillin G), but it achieves a plasma concentration of 1.5 U/ml after 2-5 hours. Active concentrations are maintained for 24 hours. Streptomycin is an aminoglycoside antibiotic with a bactericidal effect against Gram-positive bacilli (Corynebacterium spp.), Gram-negative bacilli (Escherichia coli. Klebsiella spp.), Gram-positive cocci (Staphylococcus spp. Streptococcus spp.). Streptomycin irreversibly inhibits bacterial protein synthesis, having an absolute bactericidal action. After diffusion into the channels of the bacterial

outer cell membrane, it is transported transmembrane, through an oxygen-dependent process. This active transport is inhibited under conditions of decreased intracellular pH or anaerobiosis and enhanced by antibiotics that inhibit cell wall formation, such as penicillins.
This explains the synergistic relationship between streptomycin and benzylpenicillin. Once intracellular, streptomycin binds irreversibly to the ribosomal subunit 305. with inhibition of bacterial protein synthesis and cell death.

5.2. Pharmacokinetic information

Benzylpenicillin procaine administered im is absorbed slowly from the injection site, as it dissolves. It achieves a maximum plasma concentration after 2-3 hours. Active concentrations are maintained for 24 hours. Elimination is renal, by tubular excretion.
Benzylpenicillin sodium is rapidly absorbed from the injection site after intramuscular administration. 26 min. in cattle (young animals aged 15 days), 42 min. in sheep. Plasma protein binding is low in cattle (approx. 28.5%), sheep (approx. 35.5%) and medium in horses (approx. 52-54%). It also passes into milk in small quantities. Elimination is renal, predominantly by tubular excretion. The urinary concentration is 60-100 times higher than the plasma concentration. Active tubular excretion can be interfered with by organic acids: probenecid decreases its elimination, increasing its plasma level. Hepatic elimination is reduced, the metabolites being therapeutically inactive. Small amounts are eliminated in the bile.
Streptomycin, after i.m. administration, achieves active blood concentrations that are maintained for a long time. Binding to plasma proteins is low. After i.m. administration, it is eliminated renally, in active form, achieving concentrations higher than in the blood. The half-life is 2-4 hours, but increases in renal failure.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

The product should not be mixed in the same vial or syringe with other drugs. The penicillins in the product component are incompatible with cysteine and other compounds containing the thiol group. Penicillins precipitate when combined in solutions with amphotericin, cephalothin, chlorpromazine, promethazine, oxytetracycline.
The sodium benzylpenicillin in the product component is inactivated when combined with injectable solutions stabilized with sodium pyrosulfite or sodium formaldehyde sulfoxide, when combined with solutions containing alkali or acid. as is the case with solutions of minotilin, amphotericin metaraminol, vitamin B complex, oxytetracycline, ascorbic acid, salicylic acid. also with injectable solutions that use polyethylene glycol as a vehicle.
The combination of the product with other injectable solutions may lead to the formation of transparent or cloudy mixtures due to streptomycin (e.g. with sodium salts of barbiturates and sulfonamides, phenytoin, sodium hydrogen carbonate, noradrenaline acid tartrate, calcium gluconate, sodium nitrofurantoin, amphotericin, sodium methohexitoin).
The product is incompatible with hydrazine, sodium hydrogen carbonate, lincomycin, novobiocin. protein hydrolysates, trometamol, hydrocortisone, promethazine, pentobarbital.
Streptomycin is inactivated by glucose solutions (acid), thiamine hydrochloride or histamine. Due to the streptomycin in the composition of the product, it is incompatible with substances with alkaline or acidic reaction (hydrolysis), with strong oxidants: potassium permanganate, hydrogen peroxide solution (decomposition occurs). With procaine hydrochloride it forms a colored complex.

6.2. Shelf life

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

6.3. Special precautions for storage

Store below 25°C.
Keep recommended dosage and administration.
Consult veterinarian before use.
Keep out of the reach of children.

6.4. Nature and composition of primary conditioning

Primary packaging:
Clear glass vial closed with a bromobutyl rubber stopper with an aluminium flip off seal.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

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.: 022148

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 05-11-1998

10. DATE OF REVISION OF THE TEXT

30-01-2025

MANUFACTURED BY:

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