Stempen Injection

(Penicillin G Procaine + Penicillin G Sodium + Dihydrostreptomycin Sulphate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Stempen Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial Contains:
Penicillin G Procaine……..…….3, 000,000 IU
Penicillin G Sodium……..10,00,000 IU
Dihydrostreptomycin Sulphate……...……5 gm

3. PHARMACEUTICAL FORM

Dry Powder for injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Goat, Horse, Camel, Sheep, Dogs, Cat & Poultry.

4.2. Indications for use specifying the target species

Stempen Injection is indicated in cattle, sheep and dogs in infections of the respiratory tract (pneumonia, bronchopneumonia, pleuropneumonia) and urinary tract, in case of surgical interventions requiring antibiotic treatment, in peritonitis, neonatal diseases and streptococcal mastitis, anthrax, abscesses, osteomyelitis and septicemia, caused by microorganisms sensitive to benzyl penicillin and/or dihydrostreptomycin, in particular Gram-positive (including Actinomyces spp., Arcanobacterium spp., Bacillus spp., Clostridium spp., Corynebacterium spp., Erisypelothrix spp., Listeria spp., Nocardia spp., Staphylococcus spp., Streptococcus spp., Vibrio spp.), Gram-negative (including Actinobacillus spp., Bacteroides spp., Brucella spp., Campylobacter spp., Dichelobacter nodosus, E. coli, Fusobacterium necrophorum, Haemophilus spp., Klebsiella spp., Mannheimia spp., Neisseria spp., Pasteurella spp., Proteus spp., Pseudomonas spp., Salmonella spp., Shigella spp., Yersinia spp.), Rickettsiae, Leptospires,
Spirochetes, mycoplasmas and mycobacteria.

4.3. Contraindications

Do not administer to animals with known hypersensitivity to the active substances or to any of the excipients.
Do not administer to animals with renal insufficiency.

The use of the product is contraindicated where cases of penicillin resistance are known.
Do not administer to rabbits, guinea pigs, hamsters, chinchillas and small rodents in general.

The product should not be used if the presence of beta-lactamase-producing microorganisms has been confirmed.

4.4. Special warnings for each target species

Repeated or prolonged use should be avoided by improving management practices and through cleaning and disinfection.

4.5. Special precautions for use

Special precautions for use in animals

Use normal aseptic procedures for parenteral injections.
Use of the product should be based on susceptibility testing against bacteria isolated from animals. If this is not possible, therapy should be based on local (regional, company) epidemiological information.

Use of the product deviating from the instructions provided may lead to an increase in the prevalence of resistant bacteria and may reduce the effectiveness of treatment with other antibacterial agents due to the possible emergence of cross-resistance.

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

People with known hypersensitivity to the active substances should avoid contact with the veterinary medicinal product.
Avoid contact with eyes, skin and mucous membranes. In case of accidental contact, wash the parts with plenty of water. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

Preparations containing penicillins may cause hypersensitivity phenomena and, exceptionally, anaphylactic phenomena, sometimes serious. Dihydrostreptomycin, like all aminoglycosides, may cause nephrotoxicity, ototoxicity due to lesions of the VIII cranial nerve pair and hypocalcemia (with bradycardia, decreased cardiac output and blood pressure).

4.7. Use during pregnancy and lactation or lay

In the absence of specific studies in the target species, use only in accordance with the benefit/risk assessment by the responsible veterinarian.

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

Penicillins should not be used together with bacteriostatic antibiotics. Probenecid reduces its tubular secretion, increasing its blood levels.
Nephrotoxic, ototoxic, and neurotoxic drugs may increase the incidence of dihydrostreptomycin toxicity.

4.9. Dosage and administration route

Add 20ml water for injection & shake well to make complete.

Cattle, Horse & Camel: 15ml per 200kg body weight
Sheep & Goat: 3ml per 40kg body weight

Dogs, Cat & Poultry: 0.75ml per 10kg body weight
- by intramuscular injection

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

Data not available. Do not exceed recommended doses

4.11. Withdrawal period:

Meat: Cattle and sheep: 74 days

Milk: Cattle, sheep: 168 hours (14 milkings)

Dogs, Cats & Horse: not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotics for systemic use. Combination of penicillins and other antibacterials.
ATCvet code: QJ01RA01

5.1. Pharmacodynamic properties

Stempen injection is an extemporaneous suspension based on benzyl penicillin (in the form of procaine and sodium salt) and dihydrostreptomycin sulfate. The combination exerts a constant and prolonged antibacterial action and is indicated for the treatment of infections caused by a mixed microbial flora.

Benzyl penicillin is active against Gram-positive microorganisms, on which it acts by interfering with the formation of the bacterial wall during the multiplication phase with a bactericidal action.

Dihydrostreptomycin is mainly active against Gram-negative bacteria in which it blocks protein synthesis by interacting with bacterial ribosomes, with an essentially bactericidal action.
The association therefore has an action on Gram-positive bacteria (including Actinomyces spp., Arcanobacterium spp., Bacillus spp., Clostridium spp., Corynebacterium spp., Erisypelothrix spp., Listeria spp., Nocardia spp., Staphylococcus spp., Streptococcus spp., Vibrio spp.), Gram-negative bacteria (including Actinobacillus spp., Bacteroides spp., Brucella spp., Campylobacter spp., Dichelobacter nodosus, E. coli, Fusobacterium necrophorum, Haemophilus spp., Klebsiella spp., Mannheimia spp., Neisseria spp., Pasteurella spp., Proteus spp., Pseudomonas spp., Salmonella spp.,
Shigella spp., Yersinia spp.), Rickettsiae, Leptospires, Spirochetes, Mycoplasmas and Mycobacteria.

The two active ingredients act at different locations and times on the bacterial cell and are able, in association, to exert a synergistic action by broadening the spectrum of antimicrobial activity and reducing antibiotic resistance phenomena, as some germs that have become resistant to one of the two antibiotics may be sensitive to the other.

5.2. Pharmacokinetic information

Sodium benzylpenicillin is rapidly absorbed parenterally (effective therapeutic levels after 30'), but is equally rapidly eliminated. Procain benzylpenicillin, on the other hand, is absorbed slowly over a period of 12-24 hours, reaching blood levels that are not particularly high, of late onset, but effective from a therapeutic point of view.

Benzylpenicillin binds to plasma proteins and exhibits good diffusion, which is slower than the rate of elimination. Elimination is essentially renal.
Dihydrostreptomycin is rapidly absorbed after parenteral administration. It rapidly diffuses into tissues and organic fluids, passes through the serous membranes and the placenta. Elimination occurs partly through the bile, but mainly through the kidneys in unchanged form, as it is not metabolized. STEMPEN combines a prompt action, linked to the sodium salt of penicillin, with a prolonged antibacterial activity that covers the 24-hour period, due to the presence of procainic benzylpenicillin and dihydrostreptomycin.

6. PHARMACEUTICAL INFORMATION

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after dilution or reconstitution according to instructions: 24 hours.

6.4. Special precautions for storage

Store below 30°C in a dry place.
Protect from light & moisture
Do not freeze
Shake well before use
Keep out of reach of children

6.5. Nature and composition of primary conditioning

Glass vial with bromobutyl rubber stopper and 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.: 117155

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 21-07-2023

10. DATE OF REVISION OF THE TEXT

05-06-2024