

USA Product Label

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STERILE PENICILLIN G BENZATHINE AND PENICILLIN G PROCAINE

Aspen

Active Ingredient(s): Each mL of suspension contains:

Penicillin G benzathine	150,000 units
Penicillin G procaine	150,000 units
Sodium formaldehyde sulfoxylate	1.75 mg
Lecithin	11.7 mg
Methylparaben (as preservative)	1.20 mg
Propylparaben (as preservative)	0.14 mg
Polysorbate 40	8.19 mg
Sorbitan monopalmitate	11.3 mg
Sodium citrate anhydrous	3.98 mg
Procaine hydrochloride	20.0 mg
Sodium carboxymethylcellulose	1.04 mg
Water for injection	q.s.

Indications: For the treatment of the following bacterial infections in beef cattle due to penicillin susceptible microorganisms that are susceptible to the serum levels common to this particular dosage form, such as:

1. Bacterial pneumonia (shipping fever complex) due to *Streptococcus spp., Corynebacterium pyogenes* and *Staphylococcus aureus*.

2. Upper respiratory infections such as rhinitis or pharyngitis due to Corynebacterium pyogenes.

3. Blackleg due to *Clostridium chauvoei*.

Pharmacology: Penicillin G is an antibiotic which shows a marked bactericidal effect against certain organisms during their growth phase. It is relatively specific in its action against gram-positive bacteria, but is usually ineffective against gram-negative organisms.

It is normally recommended that any bacterial infection be treated as early as possible and with a dosage that will give effective blood levels. Although the recommended dosage will give longer detectable penicillin blood levels than penicillin G procaine alone, it is recommended that a second dose be administered at 48 hours when treating a penicillin-susceptible bacterial infection.

Dosage and Administration: Warm to room temperature and shake well before using. A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized by boiling in water for 15 minutes).

Before withdrawing the solution from the bottle, disinfect the rubber cap on the bottle with a suitable disinfectant, such as 70% alcohol. The injection site should be similarly cleaned with the disinfectant. Needles of 14 to 16 gauge and not more than one (1) inch long are adequate for injections.

A subcutaneous injection should be made by pinching up a fold of the skin between the thumb and forefinger. The mid-neck region is the preferred injection site. Insert the needle under the fold in a direction approximately parallel to the surface of the body. When the needle is inserted in this manner, the medication will be delivered underneath the skin between the skin and the muscles. Proper restraint, such as the use of a chute and nose lead is needed for proper administration of the product.

Beef cattle: 2 mL per 150 lbs of body weight given subcutaneously only (2,000 units penicillin G procaine and 2,000 units penicillin G benzathine per lb of body weight). The treatment should be repeated in 48 hours.

Important: Treatment in beef cattle should be limited to two (2) doses, given by subcutaneous injection only.

Precaution(s): Store under refrigeration between 2-8°C (36-46°F). Protect from freezing.

Caution(s): Penicillin G is a substance of low toxicity. However, side effects, or so-called allergic or anaphylactic reactions, sometimes fatal, have been know to occur in animals hypersensitive to penicillin and procaine. Such reactions can occur unpredictably with varying intensity. Animals administered penicillin G should be kept under close observation for at least one-half hour. Should allergic or anaphylactic reactions occur, discontinue the use of the product and immediately administer epinephrine following the manufacturer's recommendations. Call a veterinarian.

As with all antibiotic preparations, the use of the drug may result in the overgrowth of nonsusceptible organisms, including fungi. A lack of response by the treated animal, or the development of new signs or symptoms suggests that an overgrowth of nonsusceptible organisms has occurred. In such instances, consult a veterinarian.

Since bacterial drugs may interfere with the bacteriostatic action of tetracycline, it is advisable to avoid giving penicillin in conjunction with tetracyclines.

Warning(s): Beef cattle should be withheld from slaughter for food use for 30 days following last treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Treatment in beef cattle must be limited to two (2) doses, by subcutaneous injection only. Do not inject intramuscularly.

Failure to use the subcutaneous route of administration may result in antibiotic residues in meat beyond the withdrawal time.

Restricted Drug (California).

Discussion: The use of antibiotics in the management of disease is based on an accurate diagnosis and an adequate course of treatment. When properly used in the treatment of diseases caused by penicillin-susceptible organisms, most animals treated show a noticeable improvement within 24 to 48 hours. If improvement does not occur within this period of time, the diagnosis and course of treatment should be re-evaluated. It is recommended that the diagnosis and treatment of animal diseases be carried out by a veterinarian. Since many diseases look alike but require different types of treatment, the use of professional veterinary and laboratory services can reduce treatment time, costs, and needless losses. Good housing, sanitation and nutrition are important in the maintenance of healthy animals and are essential in the treatment of disease.

Presentation: 100 mL, 250 mL, and 500 mL vials.

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