

SHAKE WELL BEFORE USING

Before using this drug, read package insert for complete product information.

Dosage and Administration

Beef Cattle: 2 mL per 150 lb body weight given subcutaneously only.



WARNINGS: Beef cattle should be withheld from slaughter for food use for thirty (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.

Store Between 2° to 8°C (36° to 46°F)

104670L02



NDC 55529-022-02

Tandem™ Pen

(sterile penicillin G benzathine and penicillin G procaine)

300,000 units per mL

Aqueous Suspension
For Subcutaneous Injection Only
Antibiotic

NADA 065-500, Approved by FDA

Net Contents: 100 mL

Norbrook

Description

Each mL of suspension contains 150,000 units penicillin G benzathine; 150,000 units penicillin G procaine; 11.7 mg lecithin; 1.75 mg sodium formaldehyde sulfoxylate; 1.20 mg methylparaben (as preservative); 0.14 mg propylparaben (as preservative); 8.19 mg polysorbate 40; 11.3 mg sorbitan monopalmitate; 3.98 mg sodium citrate anhydrous; 20 mg procaine hydrochloride; 1.04 mg sodium carboxymethylcellulose; and Water for Injection, q.s.

**Restricted Drug (California) - Use Only As Directed
Not for Use in Humans.**

Made in the UK.

Norbrook Laboratories Limited
Newry, BT35 6PU, Co. Down,
Northern Ireland

Tandem™ Pen is a trademark of
Norbrook Laboratories Limited



Lot No.:
Exp. Date:

NADA 065-500, Approved by FDA

Tandem™ Pen

(sterile penicillin G benzathine and penicillin G procaine)

300,000 units per mL

Aqueous Suspension
For Subcutaneous Injection Only
Antibiotic
Shake Well Before Using

DESCRIPTION

Each mL of suspension contains 150,000 units penicillin G benzathine; 150,000 units penicillin G procaine; 11.7 mg lecithin; 1.75 mg sodium formaldehyde sulfoxylate; 1.20 mg methylparaben (as preservative); 0.14 mg propylparaben (as preservative); 8.19 mg polysorbate 40; 11.3 mg sorbitan monopalmitate; 3.98 mg sodium citrate anhydrous; 20 mg procaine hydrochloride; 1.04 mg sodium carboxymethylcellulose; and Water for Injection, q.s.

INDICATIONS

Sterile penicillin G benzathine and penicillin G procaine in aqueous suspension is indicated for 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) (*Streptococcus* spp., *Actinomyces pyogenes*, *Staphylococcus aureus*)
2. Upper Respiratory Infections such as Rhinitis or Pharyngitis (*Corynebacterium pyogenes*).
3. Blackleg (*Clostridium chauvoei*).

DIRECTIONS FOR USE

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 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.

DOSAGE

Beef Cattle: 2 mL per 150 pound body weight GIVEN SUBCUTANEOUSLY ONLY (2,000 units penicillin G benzathine and 2,000 units penicillin G procaine per pound body weight). Treatment should be repeated in 48 hours. **IMPORTANT:** Treatment in beef cattle should be limited to two (2) doses given by subcutaneous injection only.

ADMINISTRATION

The recommended dosage for beef cattle should be administered BY SUBCUTANEOUS INJECTION ONLY. Failure to use the subcutaneous route of administration may result in antibiotic residues in meat beyond the withdrawal time.

WARNINGS

Beef cattle should be withheld from slaughter for food use for thirty (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.**

PRECAUTIONS

Exceeding the recommended doses and dosage levels may result in antibiotic residues beyond the withdrawal time. Do not inject this product intramuscularly.

Penicillin G is a substance of low toxicity. However, side effects, or so called allergic or anaphylactic reactions - sometimes fatal, have been known 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 use of the product and immediately administer epinephrine following manufacturer's recommendations; call a veterinarian.

As with all antibiotic preparations, use of this drug may result in 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 your veterinarian.

Since bacterial drugs may interfere with the bacteriostatic action of tetracyclines, it is advisable to avoid giving penicillin in conjunction with tetracyclines. Sterile penicillin G benzathine and penicillin G procaine in aqueous suspension should be stored under refrigeration below 15°C (59°F). Warm to room temperature, and shake well before using.

To report suspected adverse drug events, contact Norbrook at 1-866-591-5777 or the FDA at 1-888-FDA-VETS.

For technical assistance or to obtain a Material Safety Data Sheet, call Norbrook at 1-866-591-5777.

ACTION

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 it 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.

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 reevaluated. 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.

How supplied: Available in 100 mL vials and 250 mL vials. A 500 mL vial is available for use with automated injection equipment.

STORAGE

Store at 36° to 46°F (2° to 8°C). Protect from freezing.

Not For Use in Humans

Restricted Drug (California) - Use Only As Directed

Made in the UK

Norbrook Laboratories Limited
Newry, BT35 6PU, Co. Down,
Northern Ireland

TAKE TIME



214670I02

Norbrook 

Artwork Specification for NORBROOK PRINT ROOM from Elaine McAlpine (02/04/2012)

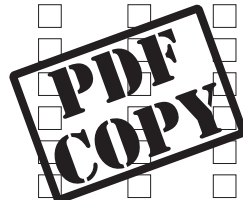
Customer..... Norbrook
Country..... USA
Product Tandem Pen
Component Insert
Resource Code 6405214670
Revision Level I02
Pharma Code..... 1133
Size A5 Single Sided
Dimensions 148 x 210 mm
Keyline (Die) Ref. N/A

COLOURS USED:

■ PMS Black

■ PMS 072

TINT OF COLOUR USED:



Norbrook

Artwork Department
Station Works, Newry, Co. Down, BT35 6JP

Ext: 3291

E-mail: elaine.mcalpine@norbrook.co.uk

APPROVED ARTWORK SENT TO PRINT BY:

Designer: Elaine McAlpine

Date: 02/04/2012