

## **PENICILLIN- penicillin g procaine injection, suspension**

**Durvet**

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### **PENICILLIN INJECTABLE**

NADA 065-010, Approved by FDA

Injectable Antibiotic

**For use in Cattle, Sheep, Swine and Horses.**

**PENICILLIN G PROCAINE INJECTABLE SUSPENSION U.S.P.**

**READ ENTIRE BROCHURE CAREFULLY**

**BEFORE USING THIS PRODUCT**

#### **Description:**

Penicillin Injectable is a suspension of penicillin G procaine in 100, 250, and 500 mL multiple dose vials. Each mL is designed to provide 300,000 units of penicillin G as procaine in a stable suspension. Penicillin G procaine is an antibacterial agent which has activity against a variety of pathogenic organisms, mainly in the Gram-positive category.

#### **Indications:**

Penicillin Injectable is indicated for treatment of bacterial pneumonia (shipping fever) caused by *Pasteurella multocida* in cattle and sheep, erysipelas caused by *Erysipelothrix rhusiopathiae* in swine, and strangles caused by *Streptococcus equi* in horses.

#### **Directions for Use:**

A thoroughly cleaned, sterile needle and syringe should be used for each injection (needles and syringes may be sterilized in boiling water for 15 minutes). Before withdrawing the solution from the bottle, disinfect the rubber cap top with 70% alcohol. The injection site should be similarly disinfected with alcohol. Needles of 16 to 18 gauge and 1 to 1.5 inches long are adequate for intramuscular injections.

In livestock intramuscular injections should be made by directing the needle of suitable gauge and length into the fleshy part of a thick muscle, such as rump, hip, or thigh region; avoid blood vessels and major nerves. Before injecting the solution, pull back gently on the plunger. If blood appears in the syringe, a blood vessel has been entered; withdraw the needle and select a different site.

#### **Dosage:**

Penicillin Injectable is administered by the intramuscular route. The product is ready for injection after warming the vial to room temperature and shaking to ensure a uniform suspension.

The daily dose of penicillin is 3,000 units per pound of body weight (1 mL per 100 lbs body weight). Continue daily treatment until recovery is apparent and for at least one day after symptoms disappear, usually in two to three days.

Treatment should not exceed four consecutive days.

No more than 10 mL should be injected at any one site. Rotate injection sites for each succeeding treatment.

#### **Care of Sick Animals:**

The use of antibiotics in the management of diseases 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 with Penicillin Injectable 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.

### **Residue Warnings:**

Exceeding the daily dosage of 3,000 units per pound of body weight, administering for more than four consecutive days, or exceeding the maximum injection site volume per injection site may result in antibiotic residues beyond the withdrawal time. Milk taken from treated dairy animals within 48 hours after the last treatment must not be used for food. Discontinue use of this drug for the following time period before treated animals are slaughtered for food:

Cattle – 14 days, Sheep – 9 days,  
Swine – 7 days.

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

### **Warning:**

Do not use in horses intended for human consumption. Not for use in humans. Keep out of reach of children.

### **Precautions:**

Intramuscular injection in cattle, sheep, and swine may result in a local tissue reaction which persists beyond the withdrawal period of 14 days (cattle), 9 days (sheep), or 7 days (swine). This may result in trim loss of edible tissue at slaughter.

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 procaine should be kept under close observation for at least one half hour. Should allergic or anaphylactic reactions occur, discontinue use of the product and call a veterinarian. If respiratory distress is severe, immediate injection of epinephrine or antihistamine following manufacturer's recommendations may be necessary.

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 suggest that an overgrowth of nonsusceptible organisms has occurred. In such instances, consult your veterinarian.

It is advisable to avoid giving penicillin in conjunction with bacteriostatic drugs such as tetracyclines.

### **Storage Conditions:**

Penicillin Injectable should be stored between 2 to 8°C (36 to 46°F).

**Restricted Drug - California. Use Only as Directed.**

Made in the UK.  
 Norbrook Laboratories Limited  
 Newry, Northern Ireland

**Distributed by:**  
**DURVET INC.**  
 Blue Springs,  
 Missouri 64014

104215I01  
 ISS: 10/10

**Principal Display Panel – 500 mL Vial Label**

NDC 30798-236-17

**durvet**

**PENICILLIN INJECTABLE**

**Sterile Penicillin G Procaine.  
 Injectable Suspension U.S.P.**

**Injectable antibiotic in aqueous  
 suspension 300,000 units/mL.**

**ANTIBIOTIC**

FOR INTRAMUSCULAR INJECTION ONLY

NADA 065-010, APPROVED BY FDA

**NET CONTENTS: 500 mL**


158

NDC 30798-236-17


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 Cattle – 14 days, Sheep – 9 days, Swine – 7 days.  
 A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.  
**Warning:**  
 Do not use in horses intended for human consumption. Not for use in humans. Keep out of reach of children.

Lot:  
 Exp:

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**PENICILLIN  
 INJECTABLE**



Sterile Penicillin G Procaine.  
 Injectable Suspension U.S.P.

Injectable antibiotic in aqueous  
 suspension 300,000 units/mL.

**ANTIBIOTIC**  
 FOR INTRAMUSCULAR INJECTION ONLY

NADA 065-010, APPROVED BY FDA

**NET CONTENTS:  
 500 mL**

Read package insert for complete product information before using the drug.

**INDICATIONS**  
 Penicillin Injectable is indicated for treatment of bacterial pneumonia (shipping fever) caused by *Pasteurella multocida* in cattle and sheep, erysipelas caused by *Erysipelothrix rhusiopathiae* in swine, and strangles caused by *Streptococcus equi* in horses.

**DESCRIPTION**  
 Each mL contains 300,000 units Penicillin G Potassium\*, 139.0 mg Procaine Hydrochloride\*, 2.0% Procaine Hydrochloride, 3.0 mg Potassium Phosphate Monobasic, 6.0 mg Potassium Phosphate Dibasic, 0.4% Sodium Formaldehyde Sulfoxylate, 0.4 mg Polysorbate 80, 2.0 mg Lecithin, 0.1% Methyl Paraben, 0.01% Propyl Paraben, 0.15% Sodium Carboxymethylcellulose, q.s. Water for Injection. \* Penicillin G Potassium and Procaine Hydrochloride react to form penicillin G procaine.

**DOSAGE**  
 Penicillin Injectable should be administered by the intramuscular route. The product is ready for injection after warming the vial to room temperature and shaking to ensure a uniform suspension. The recommended daily dosage of penicillin is 3,000 units per pound of bodyweight (one mL per 100 lbs bodyweight). Continue daily treatment until recovery is apparent and for at least one day after symptoms disappear, usually in two to three days. Treatment should not exceed four consecutive days. No more than 10 mL should be injected at any one site in adult livestock; rotate injection sites for each succeeding treatment.

**Restricted Drug - California. Use Only as Directed.**  
 Store at 2-8°C (36-46°F). SHAKE WELL BEFORE USING.

Made in the UK.  
 Norbrook Laboratories Limited  
 Newry, Northern Ireland

TAKE TIME  
 OBSERVE LABEL  
 DIRECTIONS

**PENICILLIN**

penicillin g procaine injection, suspension

**Product Information**

|                                |                 |                           |               |
|--------------------------------|-----------------|---------------------------|---------------|
| <b>Product Type</b>            | OTC ANIMAL DRUG | <b>Item Code (Source)</b> | NDC:30798-236 |
| <b>Route of Administration</b> | INTRAMUSCULAR   |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength     | Strength              |
|---|-----------------------|-----------------------|
| penicillin G procaine (UNII: 17R794ESYN) (penicillin G - UNII:Q42T66VG0C) | penicillin G procaine | 300000 [USPU] in 1 mL |

**Packaging**

| # | Item Code        | Package Description     | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------|----------------------|--------------------|
| 1 | NDC:30798-236-10 | 100 mL in 1 VIAL, GLASS |                      |                    |
| 2 | NDC:30798-236-13 | 250 mL in 1 VIAL, GLASS |                      |                    |
| 3 | NDC:30798-236-17 | 500 mL in 1 VIAL, GLASS |                      |                    |

**Marketing Information**

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NADA               | NADA065010                               | 01/01/2004           |                    |

**Labeler** - Durvet (056387798)**Registrant** - Norbrook Laboratories Limited (214580029)**Establishment**

| Name          | Address | ID/FEI    | Business Operations   |
|---------------|---------|-----------|-----------------------|
| Station Works |         | 214580029 | MANUFACTURE, ANALYSIS |

**Establishment**

| Name                       | Address | ID/FEI    | Business Operations |
|----------------------------|---------|-----------|---------------------|
| Carnbane Industrial Estate |         | 211218325 | MANUFACTURE         |

Revised: 12/2010

Durvet