

**PENONE PRO- penicillin g procaine injection, suspension
MWI/VetOne**

VETone™ PenOne Pro™ Injectable Antibiotic

NADA 065-010, Approved by FDA

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:

PenOne Pro™ 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:

PenOne Pro™ 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:

PenOne Pro™ 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 PenOne Pro™ 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:

PenOne Pro™ 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: MWI
Meridian, ID 83680
(888) 694-8381
www.vetone.net
VETone™

Principal Display Panel – 500mL Vial Label

NDC 13985-036-05

500 mL

VETone™

PenOne Pro™

Sterile Penicillin G Procaine

Injectable Suspension U.S.P.

Injectable

Injectable antibiotic in aqueous suspension

300,000 units per mL

ANTIBIOTIC

FOR INTRAMUSCULAR INJECTION ONLY

NADA 065-010,

APPROVED BY FDA

V1 503021 Net Contents: 500 mL

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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.

NDC 13985-036-05

VETone™

PenOne Pro™

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

Injectable

Injectable antibiotic in aqueous suspension
300,000 units per mL

ANTIBIOTIC
FOR INTRAMUSCULAR INJECTION ONLY

NADA 065-010,
APPROVED BY FDA

V1 503021 Net Contents: 500 mL

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

INDICATIONS
PenOne Pro™ 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
PenOne Pro™ 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). **TAKE TIME**
SHAKE WELL
BEFORE USING.

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

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Lot:
Exp:

004684L01

PENONE PRO

penicillin g procaine injection, suspension

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:13985-036	
Route of Administration	INTRAMUSCULAR			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
penicillin G procaine (UNII: 17R794ESYN) (penicillin G - UNII:Q42T66VG0C)		penicillin G procaine	300000 [USP'U] in 1 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-036-02	100 mL in 1 VIAL, GLASS		
2	NDC:13985-036-04	250 mL in 1 VIAL, GLASS		
3	NDC:13985-036-05	500 mL in 1 VIAL, GLASS		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NADA	NADA065010		06/01/2006	

Labeler - MWI/VetOne (019926120)

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