PEN-AQUEOUS- penicillin g procaine injection, suspension Aspen Veterinary Resources

Pen-Aqueous®

(penicillin G procaine)

Injectable Suspension for Cattle, Swine, Sheep & Horses

Aqueous Suspension

Antibiotic

300,000 units per mL

Restricted Drug (California) - Use Only as Directed

NADA 065-505, Approved by FDA

For Intramuscular Use Only

Sterile, Multiple Dose Vial

Net Contents: 250 mL

FOR ANIMAL USE ONLY

DESCRIPTION: Penicillin G Procaine Injectable Suspension Alternative Method is available in 100-mL, 250-mL and 500-mL multiple-dose vials. Each mL contains: penicillin g potassium 300,000 units*, procaine hydrochloride 130.8 mg*, methylparaben 1.3 mg, propylparaben 0.2 mg, sodium citrate 10 mg, sodium carboxymethylcellulose 1 mg, povidone 5 mg, lecithin 6 mg, sodium formaldehyde sulfoxylate 0.2 mg, procaine hydrochloride 20 mg, and Water for injection, q.s.

*Penicillin G Potassium and Procaine Hydrochloride react to form Penicillin G Procaine.

ACTIONS: Penicillin G is an effective bactericide in the treatment of infections caused primarily by penicillin-sensitive organisms, such as <u>Streptococcus equi</u> and <u>Erysipelothrix thusiopathiae</u>, as well as the gram negative organism <u>Pasteurella multocida</u>.

INDICATIONS: Penicillin G Procaine is indicated for the treatment of:

- 1. Cattle and sheep bacterial pneumonia (shipping fever) caused by <u>Pasteurella multocida</u>.
- 2. Swine erysipelas caused by <u>Erysipelothrix rhusiopathiae</u>.
- 2. Horses strangles caused by Streptococcus equi.

DIRECTIONS FOR USE: The suspension should be administered by deep intramuscular injection within the fleshy muscles of the hip, rump, round or thigh, or into the neck, changing the site for each injection. Do not inject subcutaneously, into a blood vessel, or near a major nerve.

Use a 16 or 18 gauge needle, 1.5 inches long. The needle and syringe should be washed thoroughly before use. The needle and syringe should then be sterilized by placing in boiling water for 15 to 20 minutes. No vial should be entered more than 15 times with a 16 gauge needle or more than 40 times with an 18 gauge needle.

The injection site should be washed with soap and water and painted with a germicide such as tincture or iodine or 70% alcohol. The product should then be administered by using the following procedure:

- 1. Warm the vial to room temperature and shake thoroughly to ensure uniform suspension.
- 2. Wipe the rubber stopper on top of the vial with a piece of absorbent cotton soaked in 70% alcohol.
- 3. Inject air into the vial for easier withdrawal.

- 4. After filling the syringe, make sure the needle is empty by pulling back the plunger of the syringe until a small air bubble appears. Then detach the needle from the syringe.
- 5. Insert the needle deep into the muscle, attach the syringe and withdraw the plunger slightly. If blood appears, withdraw the needle and insert into a different location.
- 6. Inject the dose slowly. Do not massage the site of injection.
- 7. Not more than 10 mL should be injected into one location.

Daily treatment should be continued for at least 48 hours after temperature has returned to normal and all other signs of infection have subsided. Animals treated with Penicillin G Procaine Injectable Suspension should show noticeable improvement within 36 to 48 hours.

DOSAGE: The dosage for cattle, sheep, swine, and horses is 3000 units per pound of body weight, or 1.0 mL for each 100 pounds of body weight, once daily. Treatment should not exceed 7 days in non-lactating dairy and beef cattle, sheep, and swine, or 5 days in lactating dairy cattle. If no improvement is observed within 48 hours, consult your veterinarian.

RESIDUE WARNINGS:

- 1. Not for use in horses intended for food.
- 2. Milk that has been taken from animals during treatment and for 48 hours after the last treatment must not be used for food. The daily treatment schedule should not exceed 7 days of treatment in non-lactating dairy and beef cattle, sheep and swine, or 5 days in lactating dairy cattle.
- 3. The drug should be discontinued for the following time periods before treated animals are slaughtered for food: cattle 4 days; sheep 8 days; swine 6 days; non-ruminating calves 7 days.

PRECAUTIONS: Sensitivity reactoins to penicillin and procaine, such as hives or respiratory distress, may occur in some animals. If such signs of sensitivity occur, stop medication and call your veterinarian. In some instances, particularly if respiratory distress is severe, immediate injection of epinephrine or antihistamine may be necessary.

As with any antibiotic preparation, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If this condition is suspected, stop medication and consult your veterinarian.

HOW SUPPLIED: Penicillin G Procaine Injectable Suspension is supplied in 100-mL, 250-mL, and 500-mL multiple-dose vials.

STORE BETWEEN 2⁰°C -8⁰°C (36⁰°F - 46⁰°F). AVOID FREEZING. WARM TO ROOM TEMPERATURE AND SHAKE WELL BEFORE USING.

RESTRICTED DRUG (CALIFORNIA) - USE ONLY AS DIRECTED.

DISPOSE OF CONTAINERS IN AN APPROVED LANDFILL OR BY INCINERATION.

PRECAUTIONS: Exceeding the highest recommended daily dosage of 3000 units per pound of body weight, administering at recommended levels for more than 7 consecutive days and/ or exceeding 10 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time.

WARM TO ROOM TEMPERATURE AND SHAKE WELL BEFORE USING.

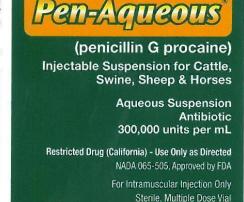
RESIDUE WARNING: Not for use in horses intended for food. Milk taken from animals during treatment and for 48 hours after the last treatment must not be used for food. Treatment should not exceed seven days in non-lactating dairy cattle and beef cattle, sheep and swine, or five days in lactating dairy cattle. Discontinue use of this drug for the following time periods before treated animals are slaughtered for food: Cattle - 4 days, Sheep - 8 days, Swine - 6 days, non-ruminating calves - 7 days.

Manufactured for: Aspen Veterinary Resources,® Ltd. Liberty, MO 64068, USA

A238B 07/12

Lot No.:

Exp. Date:



NET CONTENTS: 250 mL EACH mL OF SUSPENSION CONTAINS: Penicillin G potassium 300,000 units*, Procaine hydrochloride 130.8 mg*, Sodium citrate 10 mg, Povidone 5 mg, Lecithin 6 mg, Sodium carboxymethylcellulose 1 mg, Methylparaben 1.3 mg, Propylparaben 0.2 mg, Sodium formaldehyde sulfoxylate 0.2 mg, Procaine hydrochloride 20 mg, and Water for Injection, q.s.

*PENICILLIN G POTASSIUM AND PROCAINE HYDROCHLORIDE REACT TO FORM PENICILLIN G PROCAINE.

NOT FOR USE IN HUMANS KEEP OUT OF REACH OF CHILDREN See insert for directions and dosage. STORE BETWEEN 2°C - 8°C (36°F - 46°F). PROTECT FROM FREEZING.

Dispose of in an approved landfill or by incineration.

Pen-Aqueous® is a registered trademark of Aspen Veterinary Resources,® Ltd. Product No.: 1PEN342 8PEN364 Rev.: 07/12



PENICILLIN G PROCAINE INJECTABLE SUSPENSION

300,000 Units per mL FOR ANIMAL USE ONLY

DESCRIPTION: Penicillin G Procaine Injectable Suspension Alternative Method is available in 100-mL, 250-mL and 500-mL multiple-dose vials. Each mL contains: Active Ingredients: penicillin G potassium 300,000 units*, procaine hydrochloride 130.8 mg*. Inactive Ingredients: methylparaben 1.3 mg, propylparaben 0.2 mg, sodium citrate 10 mg, sodium carboxymethylcellulose 1 mg, povidone 5 mg, lecithin 6 mg, sodium formaldehyde sulfoxylate 0.2 mg, procaine hydrochloride 20 mg, and Water for Injection, q.s.

*Penicillin G Potassium and Procaine Hydrochloride react to form Penicillin G Procaine.

ACTIONS: Penicillin G is an effective bactericide in the treatment of infections caused primarily by penicillin-sensitive organisms, such as Streptococcus equi and Erysipelothrix rhusiopathiae, as well as the gram negative organism Pasteurella multocida.

INDICATIONS: Penicillin G Procaine is indicated for the treatment of:

- Cattle and sheep bacterial pneumonia (shipping fever) caused by Pasteurella multocida.
- 2. Swine erysipelas caused by Erysipelothrix rhusiopathiae.
- 3. Horses strangles caused by Streptococcus equi.

DIRECTIONS FOR USE: The suspension should be administered by deep intramuscular injection within the fleshy muscles of the hip, rump, round or thigh, or into the neck, changing the site for each injection. Do not inject subcutaneously, into a blood vessel, or near a major nerve.

Use a 16 or 18 gauge needle, 1.5 inches long. The needle and syringe should be washed thoroughly before use. The needle and syringe should then be sterilized by placing in boiling water for 15 to 20 minutes. No vial should be entered more than 15 times with a 16 gauge needle or more than 40 times with an 18 gauge needle.

The injection site should be washed with soap and water and painted with a germicide such as tincture of iodine or 70% alcohol. The product should then be administered by using the following procedure:

- Warm the vial to room temperature and shake thoroughly to ensure uniform suspension.
- Wipe the rubber stopper on top of the vial with a piece of absorbent cotton soaked in 70% alcohol.
- 3. Inject air into the vial for easier withdrawal.
- After filling the syringe, make sure the needle is empty by pulling back the plunger of the syringe until a small air bubble appears. Then detach the needle from the syringe.

- Insert the needle deep into the muscle, attach the syringe and withdraw the plunger slightly. If blood appears, withdraw the needle and insert it into a different location.
- 6. Inject the dose slowly. Do not massage the site of injection.
- 7. Not more than 10 mL should be injected into one location.

Daily treatment should be continued for at least 48 hours after temperature has returned to normal and all other signs of infection have subsided. Animals treated with Penicillin G Procaine Injectable Suspension should show noticeable improvement within 36 to 48 hours.

DOSAGE: The dosage for cattle, sheep, swine, and horses is 3000 units per pound of body weight, or 1.0 mL for each 100 pounds of body weight, once daily. Treatment should not exceed 7 days in non-lactating dairy and beef cattle, sheep, and swine, or 5 days in lactating dairy cattle. If no improvement is observed within 48 hours, consult your veterinarian.

RESIDUE WARNINGS:

- Not for use in horses intended for food.
- Milk that has been taken from animals during treatment and for 48 hours
 after the last treatment must not be used for food. The daily treatment
 schedule should not exceed 7 days of treatment in non-lactating dairy
 and beef cattle, sheep and swine, or 5 days in lactating dairy cattle.
- The drug should be discontinued for the following time periods before treated animals are slaughtered for food: cattle - 4 days; sheep - 8 days; swine - 6 days; non-ruminating calves - 7 days.

PRECAUTIONS: Sensitivity reactions to penicillin and procaine, such as hives or respiratory distress, may occur in some animals. If such signs of sensitivity occur, stop medication and call your veterinarian. In some instances, particularly if respiratory distress is severe, immediate injection of epinephrine or antihistamine may be necessary.

As with any antibiotic preparation, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If this condition is suspected, stop medication and consult your veterinarian.

HOW SUPPLIED: Penicillin G Procaine Injectable Suspension is supplied in 100-mL, 250-mL and 500-mL multiple-dose vials.

STORE BETWEEN 2°-8°C (36°-46°F). AVOID FREEZING. WARM TO ROOM TEMPERATURE AND SHAKE WELL BEFORE USING. RESTRICTED DRUG (CALIFORNIA) – USE ONLY AS DIRECTED. DISPOSE OF CONTAINERS IN AN APPROVED LANDFILL OR BY INCINERATION.

Manufactured For: Bimeda, Inc. • Le Sueur, MN 56058 Bimeda, Inc. is a Division of Cross Vetpharm Group Ltd. www.bimedaus.com

NADA 065-505, Approved by FDA 8PR0319-1210

PEN-AQUEOUS

penicillin g procaine injection, suspension

Product Information

Product Type	OTC ANIMAL DRUG LABEL	Item Code (Source)	NDC:46066-151
Route of Administration	INTRAMUSCULAR	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PENICILLIN G PRO CAINE (PENICILLIN G)	PENICILLIN G	300000 [USP'U] in 1 mL	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:46066-151-01	250 mL in 1 VIAL, MULTI-DOSE			
2	NDC:46066-151-02	500 mL in 1 VIAL, MULTI-DOSE			
3	NDC:46066-151-03	100 mL in 1 VIAL, MULTI-DOSE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA065505	09/22/2003	

Labeler - Aspen Veterinary Resources (627265361)

Registrant - Bimeda Inc., Division of Cross Vetpharm Gropus (060492923)

Establishment			
Name	Address	ID/FEI	Business Operations
Constant Irwindale Division of Cross Vetpharm Gropus		010569463	manufacture

Establishment			
Name	Address	ID/FEI	Business Operations
Sandoz GmbH		300220969	api manufacture

Revised: 9/2013 Aspen Veterinary Resources