

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

NOT FOR USE IN HUMANS

KEEP OUT OF REACH OF CHILDREN

DESCRIPTION: Pen-Aqueous® 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: Pen-Aqueous® is indicated for the treatment of:

1. Cattle and sheep - bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*.
2. Swine - erysipelas caused by *Erysipelothrix rhusiopathiae*.
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 Pen-Aqueous® 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 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: Pen-Aqueous is supplied in 100 mL, 250 mL, and 500 mL multiple-dose vials.

STORE BETWEEN 2° C - 8° C (36° F - 46° F). PROTECT FROM 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
www.aspenveterinaryresources.com

A2388 06/15

Lot No./Exp. Date:

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.

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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 containers in an approved landfill or by incineration.

Pen-Aqueous® is a registered trademark of Aspen Veterinary Resources*, Ltd.
Product No.: 1PEN342 8PEN364 Rev.: 06/15

TAKE TIME  OBSERVE LABEL DIRECTIONS



PEN-AQUEOUS

penicillin g procaine injection, suspension

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:46066-151
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	300000 [USP'U] in 1 mL

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

Establishment

Name	Address	ID/FEI	Business Operations
CSPC Zhongnuo (Shijiazhuang) Pharmaceutical Co., Ltd.		654663376	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Fersinsa GB DE CV		814622007	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Inner Mongolia Changsheng Pharmaceutical Co., Ltd.		545265563	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Chongqing Southwest No. 2 Pharmaceutical Factory Co., Ltd.		530826999	api manufacture