POLYMAST- hetacillin potassium gel Boehringer Ingelheim Animal Health USA Inc.

PolyMast® (hetacillin potassium)
Intramammary Infusion
For lactating cows only

Approved by FDA under NADA # 055-054

Caution:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

POLYMAST (hetacillin potassium) is a broad-spectrum agent which provides bactericidal activity against a wide range of common gram-positive and gram-negative bacteria. It is derived from 6-aminopenicillanic acid and is chemically related to ampicillin.

Each 10 mL disposable syringe contains hetacillin potassium equivalent to 62.5 mg ampicillin activity in a stable peanut oil gel. This product was manufactured by a non-sterilizing process.

Action:

Hetacillin provides bactericidal levels of the active antibiotic, ampicillin. *In vitro* studies have demonstrated susceptibility of the following organisms to ampicillin: *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Staphylococcus aureus* and *Escherichia coli*.

Indications:

For the treatment of acute, chronic or subclinical bovine mastitis. POLYMAST should be used at the first signs of inflammation or at the first indication of any alteration in the milk. Subclinical infections should be treated immediately upon determining, by C.M.T. or other tests, that the leukocyte count is elevated, or that a susceptible pathogen has been cultured from the milk.

POLYMAST has been shown to be efficacious in the treatment of mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Staphylococcus aureus* and *Escherichia coli*.

Polycillin® (ampicillin) Susceptibility Test Discs, 10 mcg, should be used to estimate the *in vitro* susceptibility of bacteria to hetacillin.

Dosage and Administration:

Infuse the entire contents of one syringe (10 mL) into each infected quarter. Repeat at 24-hour intervals until a maximum of three treatments has been given.

If definite improvement is not noted within 48 hours after treatment, the causal organism should be further investigated.

Wash the udder and teats thoroughly with warm water containing a suitable dairy antiseptic and dry, preferably using individual paper towels. Carefully scrub the teat end and orifice with 70% alcohol, using a separate swab for each teat. Allow to dry.

POLYMAST is packaged with the Opti-Sert® Protective Cap.

For partial insertion: Twist off upper portion of the Opti-Sert Protective Cap to expose 3–4 mm of the syringe tip.

For full insertion: Remove protective cap to expose the full length of the syringe tip.

Insert syringe tip into the teat canal and expel the entire contents of one syringe into each infected quarter. Withdraw the syringe and gently massage the quarter to distribute the medication.

Do not infuse contents of the mastitis syringe into the teat canal if the Opti-Sert Protective Cap is broken or damaged.

Residue Warnings:

Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food until 10 days after the latest treatment.

Precautions

Because it is a derivative of 6-aminopenicillanic acid, POLYMAST has the potential for producing allergic reactions. Such reactions are rare; however, should they occur, treatment should be discontinued and the subject treated with antihistamines, pressor amines, such as epinephrine or corticosteroids.

The drug does not resist destruction by penicillinase and, hence, is not effective against strains of staphylococcus resistant to penicillin G.

Storage:

Do not store above 25°C (77°F). Do not freeze.

How Supplied:

POLYMAST is supplied as 10 mL syringes containing 62.5 mg ampicillin activity per syringe. One display carton contains 12 syringes. One pail contains 144 syringes.

NDC 0010-4722-01 - 10 mL syringe; NDC 0010-4722-02 -12 syringes; NDC 0010-4722-03 - 144 syringes.

Opti-Sert is a registered trademark of Zoetis W LLC - used under license.

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Made in Italy

472201-01 51744638

Marketed by:

Boehringer Ingelheim Animal Health USA Inc.

Duluth, GA 30096

Principal Display Panel - 10 mL syringe label



Principal Display Panel - 12 x 10 mL syringe display carton

NDC 0010-0010-4722-02

PolyMast®

(hetacillin potassium)

Intramammary Infusion

Equivalent to 62.5 mg ampicillin

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Net Contents: 12 x 10 mL syringes

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POLYMAST hetacillin potassium gel Product Information Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:0010-4722 Route of Administration INTRAMAMMARY

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
HETACILLIN POTASSIUM (UNII: 95PFX5932Y) (AMPICILLIN - UNII:7C782967RD)	AMPICILLIN	62.5 mg in 10 mL			

Inactive Ingredients			
Ingredient Name	Strength		
PEANUT OIL (UNII: 5TL50QU0W4)			
HYDROGENATED CASTOR OIL (UNII: Z F94AP8MEY)			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0010-4722-02	12 in 1 CARTON			
1	NDC:0010-4722-01	10 mL in 1 SYRINGE, PLASTIC			
2	NDC:0010-4722-03	144 in 1 PAIL			
2	NDC:0010-4722-01	10 mL in 1 SYRINGE, PLASTIC			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA055054	09/28/2016		

Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

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