

POLYMAST- hetacillin potassium gel
Boehringer Ingelheim Vetmedica, Inc.

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

NADA 055-054, Approved by FDA

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 (hetacillin potassium) for Intramammary Infusion 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 for Intramammary Infusion 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 (hetacillin potassium) 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 (hetacillin potassium) Intramammary Infusion 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 WLLC - used under license.

PolyMast is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under license.

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472201-00 51715962

Made in Italy

Manufactured for:

Boehringer Ingelheim Vetmedica, Inc.

St. Joseph, MO 64506 U.S.A.

Syringe Label 10mL



NDC 0010-4722-01

PolyMast™

(hetacillin potassium)
**Intramammary
Infusion**

Equivalent to 62.5 mg ampicillin

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

For lactating cows only

Net Contents: 10 mL

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Each 10 mL syringe contains 62.5 mg of ampicillin activity as hetacillin potassium. This product was manufactured by a non-sterilizing process.

Dosage: One syringe per affected quarter each 24 hours for a maximum of 3 treatments. See package insert for additional dosage recommendations.

Residue Warnings: Milk taken from dairy animals within 72 hours after the latest treatment for mastitis must not be used for food.

Treated animals must not be slaughtered for food until 10 days after the latest treatment.

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

472202-00

51715956

Made in Italy

Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.



Lot

Exp

Display Carton – front and side panel

Lot
Exp

PolyMast™
(hetacillin potassium)
Intramammary Infusion
Equivalent to 62.5 mg ampicillin
Caution: Federal law restricts this drug to use
by or on the order of a licensed veterinarian.
For lactating cows only
Net Contents: 12 x 10 mL syringes
For lactating cows only

51715963

NDC 0010-4722-02

PolyMast™

(hetacillin potassium)
Intramammary Infusion

Equivalent to 62.5 mg ampicillin

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

For lactating cows only

Net Contents: 12 x 10 mL syringes
NADA 055-054, Approved by FDA

Each 10 mL syringe contains 62.5 mg
of ampicillin activity as hetacillin
potassium. This product was
manufactured by a non-sterilizing
process. This carton contains
12 alcohol pads.

Dosage: One syringe per affected
quarter each 24 hours for a maximum
of 3 treatments. See package insert for
additional dosage recommendations.

Residue Warnings: Milk
taken from dairy animals
within 72 hours after the
latest treatment for mastitis
must not be used for food.

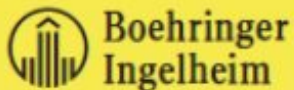
Treated animals must not
be slaughtered for food
until 10 days after the latest
treatment.

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

472203-00
Made in Italy



Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.



DCx12

Display Carton – back and side panel

NDC 0010-4722-02

PolyMast™

(hetacillin potassium)
Intramammary Infusion

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Directions for use of Opti-Sert® Protective Cap - Partial or Full Insertion



Partial Insertion:

Twist off the upper portion of the Opti-Sert Protective Cap to limit depth of insertion into the teat canal.



Full Insertion:

Remove the entire Opti-Sert Protective Cap for full insertion into the teat canal.

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

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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: ZF94AP8MEY)	

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 Vetmedica, Inc. (007134091)

Revised: 9/2018

Boehringer Ingelheim Vetmedica, Inc.