DRY-CLOX- cloxacillin benzathine gel Boehringer Ingelheim Animal Health USA Inc.

Dry-Clox® (cloxacillin benzathine) Intramammary Infusion FOR USE IN DRY COW ONLY

Approved by FDA under NADA # 055-058

Caution:

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

Description:

DRY-CLOX (cloxacillin benzathine) is a product which provides bactericidal activity against gram-positive bacteria in the dry cow. The active agent, cloxacillin benzathine, is a sparingly soluble salt of the semisynthetic penicillin, cloxacillin. Cloxacillin is a derivative of 6-aminopenicillanic acid, and therefore is chemically related to other penicillins. It has, however, the antibacterial properties described below, which distinguish it from certain other penicillins.

Each 10 mL disposable syringe contains cloxacillin benzathine equivalent to 500 mg of cloxacillin activity in a stable peanut oil gel. This product was manufactured by a non-sterilizing process.

Storage:

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

Action:

In the non-lactating mammary gland, DRY-CLOX provides bactericidal levels of the active antibiotic, cloxacillin, for a prolonged period of time. This prolonged activity is due to the low solubility of the cloxacillin benzathine and to the slow-release oil-gel base. This prolonged contact between the antibiotic and the pathogenic organism enhances the probability of a bacteriological cure.

Cloxacillin is not destroyed by the enzyme, penicillinase, and therefore, is active against penicillin-resistant strains of *Staphylococcus aureus*. It is also active against non-penicillinase-producing *Staphylococcus aureus* as well as *Streptococcus agalactiae*.

The class disc, Methicillin 5 mcg, should be used to estimate the *in vitro* susceptibility of bacteria to cloxacillin.

Indications:

For the treatment of mastitis in dairy cows during the dry period.

DRY-CLOX has been shown by extensive clinical studies to be efficacious in the treatment of mastitis in dry cows, when caused by *Streptococcus agalactiae* and *Staphylococcus aureus* including penicillin-resistant strains.

Treatment of the dry cow with DRY-CLOX is indicated in any cow known to harbor any of these organisms in the udder at drying off, or which has had repeated attacks of mastitis during the previous lactation, or is affected with mastitis at drying off, if caused by susceptible organisms.

Dosage for Dry Cows:

Infuse the contents of one syringe (10 mL) into each quarter following the last milking. See Directions for Use.

Directions for Use:

DRY-CLOX is for use in dry cows only. Administer immediately after the last milking. **Use no later than 30 days prior to calving.**

Completely milk out all four quarters. The udder and teats should be thoroughly washed with warm water containing a suitable dairy antiseptic and dried, 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.**

DRY-CLOX 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 syringe into the 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.

Precautions:

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

Residue Warnings:

- 1. For use in dry cows only.
- 2. Not to be used within 30 days of calving.
- 3. Any animal infused with this product must not be slaughtered for food until 30 days

after the latest infusion.

How Supplied:

DRY-CLOX (cloxacillin benzathine) is supplied as 10 mL syringes containing 500 mg of cloxacillin activity per syringe. One display carton contains 12 syringes. One pail contains 144 syringes.

NDC 0010-4720-02 - 12 syringes NDC 0010-4720-03 - 144 syringes

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

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Made in Italy

Marketed by:

Boehringer Ingelheim Animal Health USA Inc. Duluth, GA 30096

51744632

472001-04

Principal Display Panel - Syringe Label

Dry-Clox®

(cloxacillin benzathine)

Intramammary Infusion

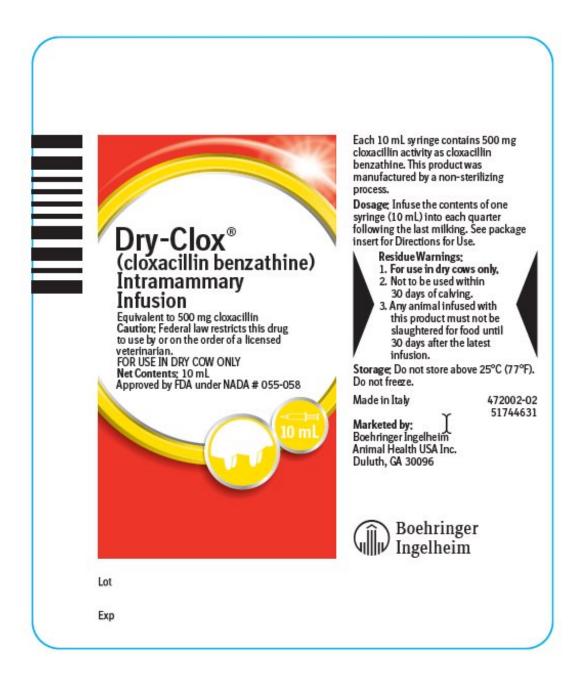
Equivalent to 500 mg cloxacillin

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FOR USE IN DRY COW ONLY

Net Contents: 10 mL

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Principal Display Panel - 12 x 10 mL display carton

NDC 0010-4720-02

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(cloxacillin benzathine)

Intramammary Infusion

Equivalent to 500 mg cloxacillin

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FOR USE IN DRY COW ONLY

Net Contents: 12 x 10 mL syringes

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DRY-CLOX

cloxacillin benzathine gel

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Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:0010-4720

Route of Administration INTRAMAMMARY

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

CLOXACILLIN BENZATHINE (UNII: AC79L7PV2G) (CLOXACILLIN - UNII: O6X5QGC2VB)

CLOXACILLIN 500 mg in 10 mL

Inactive Ingredients

Ingredient Name Strength

PEANUT OIL (UNII: 5TL50QU0W4)

HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)

| P | Packaging | | | | | | |
|---|------------------|---------------------|-----------------------------|--------------------|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | |
| 1 | NDC:0010-4720-02 | 12 in 1 CARTON | | | | | |
| 1 | NDC:0010-4720-01 | 10 mL in 1 SYRINGE | | | | | |
| 2 | NDC:0010-4720-03 | 144 in 1 PAIL | | | | | |
| 2 | NDC:0010-4720-01 | 10 mL in 1 SYRINGE | | | | | |

| Marketing Information | | | | | |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| NADA | NADA055058 | 03/11/1975 | | | |
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Labeler - Boehringer Ingelheim Animal Health USA Inc. (007134091)

Revised: 5/2022 Boehringer Ingelheim Animal Health USA Inc.