

ORBENIN-DC- cloxacillin benzathine suspension
Merck Sharp & Dohme Corp.

Orbenin-DC™
(cloxacillin benzathine
intramammary infusion)

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

DESCRIPTION: Orbenin-DC (cloxacillin benzathine intramammary infusion) is a stable, nonirritating suspension of cloxacillin benzathine containing the equivalent of 500 mg of cloxacillin per disposable syringe. Orbenin-DC is manufactured by a nonsterilizing process.

Cloxacillin benzathine is a semisynthetic penicillin derived from the penicillin nucleus, 6-amino-penicillanic acid. Cloxacillin benzathine is the benzathine salt of 6-[3-(2-chlorophenyl)-5-methylisoxazolyl-4-carboxamido] penicillanic acid.

The low solubility of Orbenin-DC results in an extended period of activity. Therefore, directions for use should be followed explicitly.

ACTION: Cloxacillin benzathine is bactericidal in action against susceptible organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptide. It is active against gram-positive organisms associated with mastitis such as *Staphylococcus aureus* and *Streptococcus agalactiae* and, because of its resistance to penicillinase, penicillin G-resistant staphylococci which may be the cause of mastitis.

Appropriate laboratory tests should be conducted, including in vitro culturing and susceptibility tests on pretreatment milk samples collected aseptically.

SUSCEPTIBILITY TEST: The Kirby-Bauer¹ procedure, utilizing antibiotic susceptibility disks, is a quantitative method that may be adapted to determining the sensitivity of bacteria in milk to Orbenin-DC.

For testing the effectiveness of Orbenin-DC in milk, follow the Kirby-Bauer procedure using the 1 mcg oxacillin susceptibility disk. Zone diameters for interpreting susceptibility are:

| Resistant | Intermediate | Susceptible |
|------------------|---------------------|--------------------|
| ≤ 10 mm | 11-12 mm | ≥ 13 mm |

¹ Bauer AW, Kirby WMM, Sherris JC, et al: Antibiotic testing by a standardized single disk method, *Am J Clin Path* 45:493, 1966. Standardized Disk Susceptibility Test, *Federal Register* 37:20527-29, 1972.

INDICATIONS: Orbenin-DC is indicated in the treatment and prophylaxis of bovine mastitis in nonlactating cows due to *Staphylococcus aureus* and *Streptococcus agalactiae*.

CONTRAINDICATIONS: Because cloxacillin benzathine is relatively insoluble, Orbenin-

DC's activity will be prolonged. Therefore, Orbenin-DC should not be used for the occasional cow which may have a dry period of less than 4 weeks. This precaution will avoid residues in the milk following removal of the colostrum.

WARNINGS: For use in dry cows only. Do not use within 4 weeks (28 days) of calving. Treated animals must not be slaughtered for food purposes within 4 weeks (28 days) of treatment.

PRECAUTION: Because it is a derivative of 6-amino-penicillanic acid, Orbenin-DC has the potential for producing allergic reactions. Such reactions are rare; however, should they occur, the subject should be treated with the usual agents (antihistamines, pressor amines).

DOSAGE AND ADMINISTRATION: At the last milking of lactation, milk the cow out normally. Clean and disinfect the teats with alcohol swabs provided in the pail and infuse 1 syringe of Orbenin-DC, which has been warmed to room temperature, into each quarter. Do not milk out. The cow may be milked as usual when she calves.

The extent of subclinical and latent mastitis in a herd is frequently greater than suspected. In untreated herds a significant buildup of subclinical mastitis may occur during the dry period, which results in clinical severity after a few lactations. The adverse influence of subclinical mastitis on milk yield, the risk of cross-infection, and the chance of clinical mastitis flare-up make it necessary to treat the matter as a herd problem. Clinical studies have proven the value of treating all the cows in heavily infected herds as they are dried off. When the herd infection has been reduced, it may be desirable to be more selective in treating infected quarters.

Each pail contains 144 alcohol wipes to facilitate proper cleaning and disinfecting of the teat orifice.

HOW SUPPLIED: Orbenin-DC is supplied in pails of 144 single dose syringes with 144 alcohol wipes. Each disposable syringe contains 500 mg of cloxacillin as the benzathine salt in 7.5 g of suitable base.

Do Not Store Above 24°C (75°F)

Orbenin-DC™ is a trademark used by Intervet Inc.

Approved by FDA under NADA # 055-069

TAKE TIME  OBSERVE
LABEL
DIRECTIONS

Manufactured by: G.C. Hanford Mfg. Co.
Syracuse, NY 13201

© 2015-2021 Intervet Inc., a subsidiary of Merck & Co., Inc., Madison, NJ 07940, US
All rights reserved.
Rev. 08/2021

359106 R3
PAL16270 01

MERCK

Animal Health

PRINCIPAL DISPLAY PANEL - 7.5 g Syringe Label

Orbenin-DC™
(cloxacillin benzathine intramammary infusion)
7.5 g

DRY COW

Long Acting Formula

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under NADA # 055-069.

Unvarnished Area

Orbenin-DC™ 7.5 g
(cloxacillin benzathine intramammary infusion)
DRY COW (VACA SECA)
Long Acting Formula

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under NADA # 055-069.

Each 7.5-g, single-dose, disposable syringe contains cloxacillin benzathine equivalent to 500 mg of cloxacillin in a suitable base for treatment and prophylaxis of bovine mastitis in nonlactating cows due to *Staphylococcus aureus* and *Streptococcus agalactiae*. Infuse 1 syringe into each quarter at time of drying-off. Manufactured by a nonsterilizing process.

Warnings: For use in dry cows only. Do not use within 4 weeks (28 days) of calving. Treated animals must not be slaughtered for food purposes within 4 weeks (28 days) of treatment.

Do Not Store Above 24°C (75°F)
Read Insert for Complete Directions

Manufactured by:
G.C. Hanford Mfg. Co.
Syracuse, NY 13201
LBL15479 05

TAKE TIME  OBSERVE LABEL DIRECTIONS

Copyright © 2022 Merck & Co., Inc.,
Rahway, NJ, USA and its affiliates.
All rights reserved. Rev. 10/2022



PRINCIPAL DISPLAY PANEL - 7.5 g Syringe Carton

Orbenin-DC™
(cloxacillin benzathine
intramammary infusion)

DRY COW

Intramammary Infusion

short tip

LONG-ACTING FORMULA

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

12 single-dose (7.5 g),
disposable syringes

Approved by FDA under NADA # 055-069

MERCK

Animal Health

Orbenin-DC™

(cloxacillin benzathine
intramammary infusion)

**DRY COW
(VACA SECA)**

**Intramammary Infusion
(Infusión intramamaria)**

**LONG-ACTING FORMULA
(FÓRMULA DE LARGA ACCIÓN)**



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

**12 single-dose (7.5 g),
disposable syringes**



Approved by FDA under NADA # 055-009



 **MERCK**
Animal Health

Orbenin-DC™

(cloxacillin benzathine
intramammary infusion)

**DRY COW
(VACA SECA)**

**Intramammary Infusion
(Infusión intramamaria)**

**LONG-ACTING FORMULA
(FÓRMULA DE LARGA ACCIÓN)**

READ RESIDUE WARNING




**DO NOT SLAUGHTER
COW FOR 28 DAYS AFTER
LAST TREATMENT**



Do not print
Lot and Exp will be embossed in this area

12 single-dose (7.5 g), disposable syringes
(Infusión intramamaria)
Intramammary Infusion
(Fórmula de Larga Acción)
LONG-ACTING FORMULA
(VACA SECA)
DRY COW
(cloxacillin benzathine
intramammary infusion)



Orbenin-DC™

Orbenin-DC™

(cloxacillin benzathine
intramammary infusion)
DRY COW (VACA SECA)

Description: Each single-dose, disposable syringe contains cloxacillin benzathine equivalent to 500 mg of cloxacillin in 7.5 g of a suitable base. Orbenin-DC is manufactured by a nonsterilizing process.

Indications: For the treatment and prophylaxis of bovine mastitis in non-lactating cows due to *Staphylococcus aureus* and *Streptococcus agalactiae*.

Dosage and Administration: At the last milking of lactation, milk the cow out normally. Clean and disinfect the teats with alcohol swabs provided in the carton, and infuse 1 syringe of Orbenin-DC, which has been warmed to room temperature, into each quarter. Do not milk out. The cow may be milked as usual when she calves.

Warnings: For use in dry cows only. Do not use within 4 weeks (28 days) of calving. Treated animals must not be slaughtered for food purposes within 4 weeks (28 days) of treatment.

Precaution: Administration of this product in any manner other than described under Dosage and Administration may result in drug residues.

Veterinary Use Only—Not for Human Use
Keep Out of Reach of Children
Discard Empty Container—Do Not Reuse
Do Not Store Above 24°C (75°F)
Read Insert for Complete Directions

Manufactured by:
G.C. Hanford Mfg. Co.
Syracuse, NY 13201

Copyright © 2022 Merck & Co., Inc.,
Rahway, NJ, USA and its affiliates.
All rights reserved. Rev. 10/2022

CTN15481 05



Orbenin-DC™

(cloxacillin benzathine
intramammary infusion)

**DRY COW
(VACA SECA)**
Intramammary Infusion
(Infusión intramamaria)

LONG-ACTING FORMULA
(FÓRMULA DE LARGA ACCIÓN)

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

**12 single-dose (7.5 g),
disposable syringes**

Approved by FDA under NADA # 055-069



ORBENIN-DC

cloxacillin benzathine suspension

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:0061-8134 |
| 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 7.5 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:0061-8134-01 | 12 in 1 CARTON | | |
| 1 | | 7.5 mL in 1 SYRINGE | | |
| 2 | NDC:0061-8134-06 | 144 in 1 PAIL | | |
| 2 | | 7.5 mL in 1 SYRINGE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NADA | NADA055069 | 03/11/1975 | |

Labeler - Merck Sharp & Dohme Corp. (001317601)

