

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

Orbenin-DC®
(benzathine cloxacillin)

F-27865909

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.

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

Benzathine cloxacillin is a semisynthetic penicillin derived from the penicillin nucleus, 6-amino-penicillanic acid. Benzathine cloxacillin 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: Benzathine cloxacillin 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 benzathine cloxacillin 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 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.

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 carton contains 12 alcohol swabs to facilitate proper cleaning and disinfecting of the teat orifice.

HOW SUPPLIED: Orbenin-DC is supplied in cartons of 12 single-dose syringes with 12 alcohol swabs. 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 owned by and used under license from SmithKline Beecham.

NADA #55-069, Approved by FDA

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



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10/03

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Printed in USA

PRINCIPAL DISPLAY PANEL - 12 Syringe Carton

Orbenin-DC®
(benzathine cloxacillin)

DRY COW

short tip

Intramammary Infusion

LONG-ACTING FORMULA

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

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Schering-Plough Animal Health Corp.

Orbenin-DC[®]

(benzathine cloxacillin)

**DRY COW
(VACA SECA)**

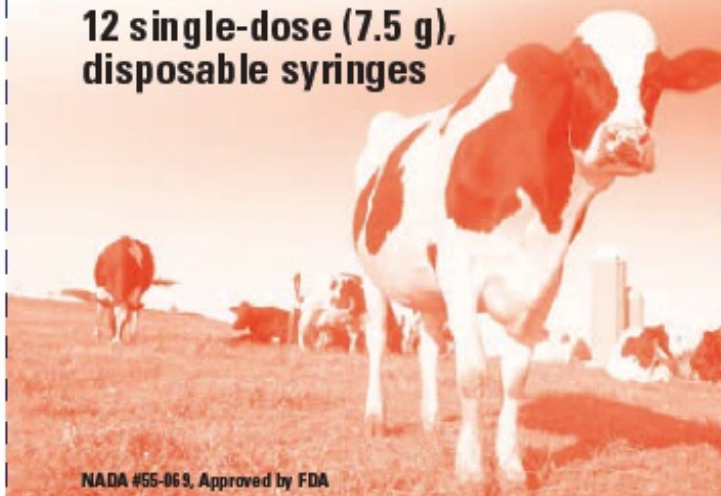


**Intramammary Infusion
(Infusión intramamaria)**


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(VACA SECA)**

**Intramammary Infusion
(Infusión intramamaria)**

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

READ RESIDUE WARNING 



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

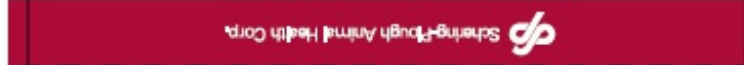


 Schering-Plough Animal Health Corp.





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 (benzathine cloxacillin)
 DRY COW
 (VACA SECA)
 LONG-ACTING FORMULA
 (FÓRMULA DE LARGA ACCIÓN)
 12 single-dose (7.5 g),
 disposable syringes



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 (benzathine cloxacillin)

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 (VACA SECA)**

Description: Each single-dose, disposable syringe contains benzathine cloxacillin 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

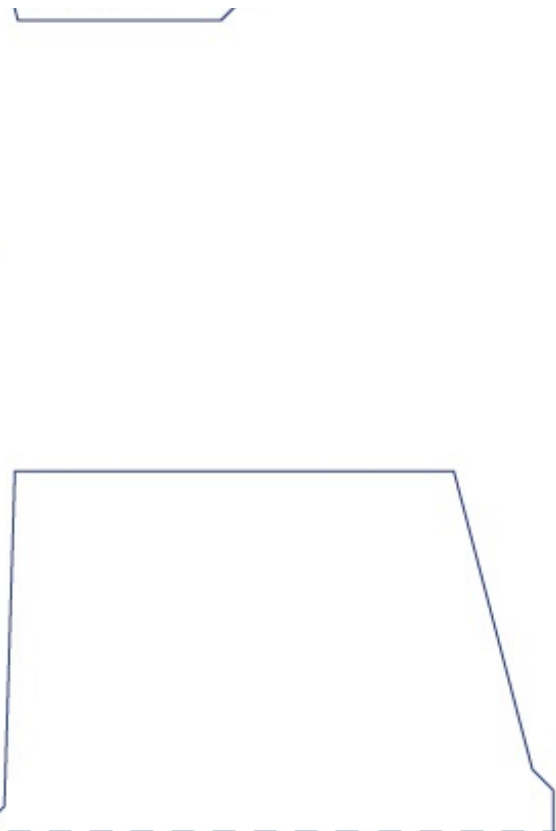
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Manufactured by:
 G.C. Hanford Mfg. Co.
 Syracuse, NY 13201

Schering-Plough Animal Health

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Made in the USA



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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		

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)