PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ L.A. 200 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Orbenin L.A. Intramammary Suspension (Long-Acting).

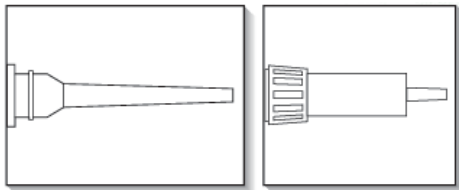
Each syringe contains 200 mg cloxacillin as Cloxacillin Sodium in 3 g of suspension.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

12 syringes



Conventional Short

Optional Nozzle Length

5. TARGET SPECIES

Dairy cows and ewes

6. INDICATION(S)

For the treatment of lactating dairy cows and ewes

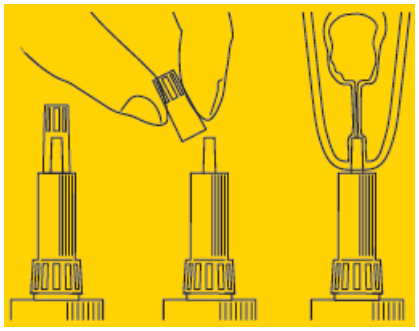
7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions: See enclosed leaflet.

Orbenin L.A. comes with a nozzle adaptor to give you the choice of short or conventional nozzle lengths.

Use of the short nozzle avoids full penetration of the teat canal: when practical this option is recommended.

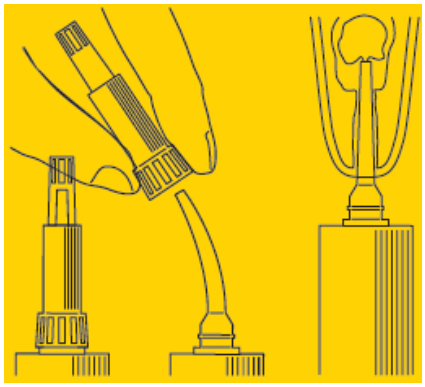
How to select and use the short nozzle:



How to select: Hold top section of the white cap between forefingers and thumb. Bend top of cap and break to remove as shown in diagram. Do not touch the nozzle with your fingers.

How to use: Insert only the inner white part of the nozzle into the teat as indicated in the diagram. Apply gentle and continuous pressure on the syringe plunger until the suspension is expressed into the teat canal.

How to select and use the conventional nozzle:



How to select: Hold base of white cap between forefinger and thumb. Bend whole cap and pull to remove as shown in diagram. Do not touch the nozzle with your fingers.

How to use: Insert the nozzle in the usual way. Apply gentle and continuous pressure on the syringe plunger until the suspension is expressed into the teat canal.

8. WITHDRAWAL PERIOD

Cattle (milk) 96 hours.

Sheep (milk): Not to be used in ewes producing milk for human consumption.

Cattle & sheep (meat and offal): 7 days.

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa.

Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations. Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Wash hands after use.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in a dry place.

Individual syringes must only be used once.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only

POM-V

To be supplied only on veterinary prescription

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co. Dublin
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 60021/3012

17. MANUFACTURER’S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Syringe Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ L.A. 200 mg Intramammary Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each syringe contains 200 mg of cloxacillin as Cloxacillin Sodium in 3 g of suspension.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 g

4. ROUTE(S) OF ADMINISTRATION

For the treatment of lactating dairy cows and ewes.

5. WITHDRAWAL PERIOD

Cattle (milk): 96 hours.

Sheep (milk): Not to be used in ewes producing milk for human consumption.

Cattle & sheep (meat and offal): 7 days.

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expires end:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep out of the sight and reach of children.

Do not store above 25°C. Store in a dry place.

See package leaflet for user warnings

Vm 60021/3012

POM-V

To be supplied only on veterinary prescription.

Zoetis Belgium S.A.

PACKAGE LEAFLET FOR: Orbenin™ L.A. 200 mg Intramammary Suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co. Dublin
Ireland

Batch release site not listed

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ L.A. 200 mg Intramammary Suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Orbenin L.A. is an off-white, stable suspension of cloxacillin as the sodium salt in a long acting base prepared under sterile conditions.

It is presented in syringes containing 200 mg cloxacillin in 3 g of suspension.

The active material is a semi-synthetic penicillin.

4. INDICATIONS

Orbenin L.A. is specially formulated for the treatment of clinical mastitis in lactating cows. The product is also indicated as an intramammary infusion in ewes at weaning for the treatment and prevention of mastitis.

Orbenin L.A. is effective against Gram-positive organisms associated with mastitis. It is effective against *Streptococcus agalactiae* and other streptococcal species, penicillin-resistant and sensitive staphylococci and *Arcanobacterium pyogenes*.

Unlike natural penicillins, Orbenin L.A. is not destroyed by staphylococcal penicillinase. It is therefore active against penicillin-resistant staphylococci which are an important cause of mastitis.

The antibiotic is bactericidal at the concentrations established in the udder and is non-irritant to the udder tissues.

In staphylococcal and certain forms of streptococcal mastitis, an adequate duration of treatment is important in achieving both clinical and bacteriological cures.

Orbenin L.A. with its slow release is designed to meet these requirements.

5. CONTRAINDICATIONS

Not for use in ewes producing milk for human consumption.

6. ADVERSE REACTIONS

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7. TARGET SPECIES

Cows and ewes

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cows

Dosage: A course of three infusions per infected quarter - one syringe given every 48 hours. Individual syringes must only be used once.

Ewes

Dosage: A single infusion should be made into each udder half at weaning.

9. ADVICE ON CORRECT ADMINISTRATION

Cows

Administration: Clean and disinfect the teat after milking. Insert nozzle into the teat and apply gentle and continuous pressure until the suspension is expressed. The treated quarter(s) may be milked out at the next normal milking time.

Ewes

Administration: It is important that a simple hygienic procedure is followed. One operator should turn up and hold each ewe whilst a second person carries out the infusion technique.

Clean and disinfect each teat end.

Appose the syringe nozzle to the teat orifice and apply gentle, continuous pressure to express the suspension into the udder. Actual cannulation of the teat orifice is not necessary nor desirable.

Use a fresh syringe for each udder half to avoid the possibility of cross contamination during infusion.

10. WITHDRAWAL PERIODS

Cattle (milk): 96 hours.

Sheep (milk): Not to be used in ewes producing milk for human consumption.

Cattle & sheep (meat and offal): 7 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Store in a dry place.

Keep out of the sight and reach of children.

12. SPECIAL WARNINGS

Operator Warnings

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa.

Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Wash hands after use.

For animal treatment only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

15. OTHER INFORMATION

Orbenin L.A. is supplied in cartons of 12 syringes.

POM-V

To be supplied only on veterinary prescription.

Vm 60021/3012

Product Summary

- Orbenin L.A. is specially prepared for the treatment of mastitis in dairy cows during lactation.
- Orbenin L.A. is also indicated as an intramammary infusion in ewes at weaning for the treatment and prevention of mastitis.
- Orbenin L.A. is bactericidal, with activity against penicillin-resistant and sensitive staphylococci, streptococci and A. pyogenes.
- The duration of treatment provided by the recommended dosage makes Orbenin L.A. particularly useful when staphylococci are known or suspected to be involved.

Gavin Hall

Approved: 19 November 2024