PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Extra Dry Cow 600 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cloxacillin benzathine

Orbenin Extra Dry Cow is an off-white stable intramammary suspension of cloxacillin as the benzathine salt in a long acting mineral oil base prepared under sterile conditions. It is presented in syringes containing 600 mg cloxacillin as Cloxacillin benzathine in 3.6 g of suspension.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

24 syringes

Conventional Short

Optional nozzle length

5. TARGET SPECIES

-

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use:

Thoroughly clean and disinfect teat end before use.

Swab teat end with surgical spirit, and taking care to avoid contamination of the syringe nozzle, infuse contents of one syringe into each quarter immediately after last milking.

After infusion it is advisable to dip each teat in an authorised teat dip.

For further directions see enclosed leaflet.

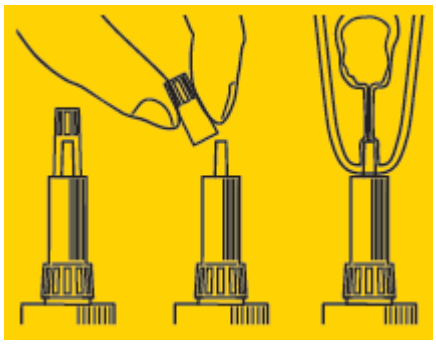
Orbenin Extra Dry Cow comes with a nozzle adaptor to give you the choice of short or conventional nozzle lengths.

Use of 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 the 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.



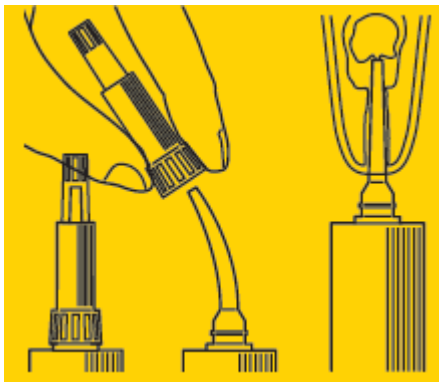
How to use:

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 the 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

The following applies to the use of Orbenin Extra Dry Cow either alone or in combination with Orbeseal.

Not intended for use in cows with dry periods of 42 days or less. Milk for human consumption may only be taken from 96 hours after calving. Should a cow calve earlier than 42 days after treatment, milk may not be used for human consumption for 42 days plus 96 hours after last treatment. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in the lactating cow. If a lactating cow is accidentally infused, milk should be withheld from the bulk supply for 46 days.

WARNING: To avoid contamination, do not touch uncapped nozzle with fingers at any time.

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

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

The syringe may only be used once. Part used syringes must be discarded.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

Orbenin is a trademark owned by, and used under licence from, Glaxo Group Limited.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5211

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Bucket}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Extra Dry Cow 600 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Cloxacillin benzathine

Orbenin Extra Dry Cow is an off-white stable intramammary suspension of cloxacillin as the benzathine salt in a long acting mineral oil base prepared under sterile conditions. It is presented in syringes containing 600 mg cloxacillin as Cloxacillin benzathine in 3.6 g of suspension.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

120 syringes

5. TARGET SPECIES

-

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use:

Thoroughly clean and disinfect teat end before use.

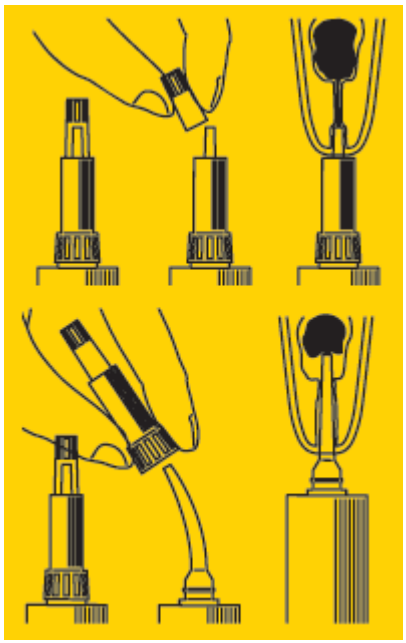
Swab teat end with surgical spirit, and taking care to avoid contamination of the syringe nozzle, infuse contents of one syringe into each quarter immediately after last milking.

After infusion it is advisable to dip each teat in an authorised teat dip.

For further directions see enclosed leaflet.

Orbenin Extra Dry Cow comes with a nozzle adaptor to give you the choice of short or conventional nozzle lengths.

Use of 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 the 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 the 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

The following applies to the use of Orbenin Extra Dry Cow either alone or in combination with Orbeseal.

Not intended for use in cows with dry periods of 42 days or less. Milk for human consumption may only be taken from 96 hours after calving. Should a cow calve earlier than 42 days after treatment, milk may not be used for human consumption for 42 days plus 96 hours after last treatment. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in the lactating cow. If a lactating cow is accidentally infused, milk should be withheld from the bulk supply for 46 days.

WARNING: To avoid contamination, do not touch uncapped nozzle with fingers at any time.

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

Exp

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

The syringe may only be used once. Part used syringes must be discarded.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

Orbenin is a trademark owned by, and used under licence from, Glaxo Group Limited.

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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5211

17. MANUFACTURER’S BATCH NUMBER

Lot

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Extra Dry Cow 600 mg Intramammary Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each syringe contains 3.6 g of suspension comprising 600 mg cloxacillin as Cloxacillin benzathine in a long-acting base.

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

3.6 g

4. ROUTE(S) OF ADMINISTRATION

-

5. WITHDRAWAL PERIOD

Meat: 28 days. Milk: 42 days plus 96 hours.

See package leaflet for details.

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep out of the sight and reach of children.

Vm 42058/5211

POM-V

To be supplied only on veterinary prescription.

Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

PACKAGE LEAFLET FOR:

Orbenin™ Extra Dry Cow 600 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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Batch release site not listed

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Extra Dry Cow 500 mg Intramammary Suspension

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

Orbenin Extra Dry Cow is an off-white stable suspension of cloxacillin as Cloxacillin benzathine in a long-acting base, prepared under sterile conditions. It is presented in syringes containing 600 mg cloxacillin as cloxacillin benzathine, in 3.6 g of suspension.

4. INDICATIONS

Orbenin Extra Dry Cow is recommended for routine use in cows at drying off, to treat existing intramammary infections and to provide prolonged protection against new infections during the dry period.

The concomitant use of Orbeseal at drying off provides additional protection against the ingress of udder pathogens, contributing to preventing both subclinical infections and clinical mastitis during early lactation.

Orbenin is active against Gram-positive organisms associated with mastitis. These include: *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, penicillin-resistant and sensitive staphylococci, and *Actinomyces pyogenes*. Orbenin is bactericidal in action and is not destroyed by staphylococcal ß-lactamase. It is, therefore, active against penicillin-resistant staphylococci which are an important cause of mastitis.

The Orbenin Extra Dry Cow formulation is non-irritant to udder tissue and maintains effective antibiotic levels in the majority of quarters for at least 7 weeks after infusion. It thus provides an extended period of protection against new infection.

5. CONTRAINDICATIONS

Do not use in the lactating cow. If a lactating cow is accidentally infused, milk should be withheld from the bulk supply for 46 days or less time if testing shows to be free of antibiotic residues.

6. ADVERSE REACTIONS

-

7. TARGET SPECIES

Cows

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

One syringe per quarter immediately after the final milking of a lactation.

9. ADVICE ON CORRECT ADMINISTRATION

At drying off clean and disinfect the teat with surgical spirit following the last milking.

Take care to avoid contamination of the syringe nozzle, insert nozzle into teat and apply gentle and continuous pressure until suspension is expressed. After infusion it is advisable to dip each teat in a licensed teat dip.

10. WITHDRAWAL PERIODS

The following applies to the use of Orbenin Extra Dry Cow either alone or in combination with Orbeseal.

Not intended for use in cows with dry periods of 42 days or less. Milk for human consumption may only be taken from 96 hours after calving. If calving occurs before 42 days after last treatment, milk for human consumption may only be taken from 42 days plus 96 hours after last treatment.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Keep out of the sight and reach of children.

The syringe may only be used once. Part used syringes must be discarded.

12. SPECIAL WARNINGS

Operator Warnings

Penicillins and cepalosporins 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 reaction 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 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 may 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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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 Extra Dry Cow is supplied in cartons of 24 syringes. An economy pack containing 120 syringes is also available.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/5211

Product Summary

- Effective dry cow therapy- contains cloxacillin, an established and proven antibiotic for intramammary use at drying off.
- Prolonged protection against new infection during the dry period-long-acting base maintains effective antibiotic levels in the majority of quarters for at least 7 weeks after infusion.
- Bactericidal action- kills the Gram-positive bacteria associated with mastitis, including penicillin-resistant and sensitive staphylococci, streptococci and *A. pyogenes*.
- Non-irritant to udder tissues.

Orbenin is a trademark owned by, and used under licence from, Glaxo Group Limited.

Gavin Hall

Approved: 20 May 2025