

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Dry Cow 500 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Orbenin Dry Cow is a sterile suspension of cloxacillin as the benzathine salt in a long acting mineral oil base, presented in syringes containing 500 mg cloxacillin as cloxacillin benzathine in 3 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.

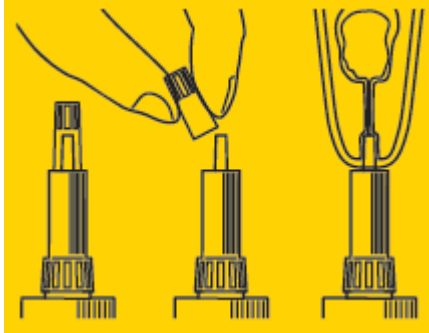
Orbenin Dry Cow comes with a nozzle adaptor to give you the choice of short or conventional nozzle lengths.

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.



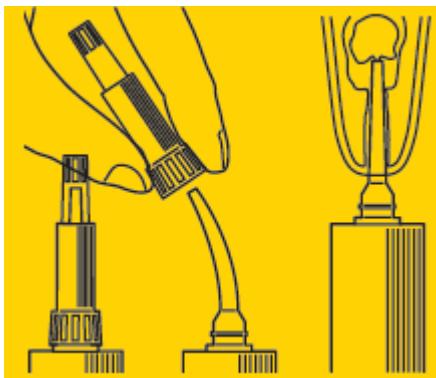
How to use:

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

Not intended for use within 30 days of calving. Milk for human consumption may only be taken from 204 hours after calving. Should a cow calve earlier than 30 days after

treatment, milk for human consumption may only be taken after 30 days plus 204 hours from 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 lactating cows are accidentally infused, milk should be withheld from the bulk supply for 30 days or less if testing shows it to be free from antibiotic residues.

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

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep the syringes in the outer carton.

The syringe must 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 42058/4088

17. MANUFACTURER’S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Bucket}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Dry Cow 500 mg Intramammary Suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Orbenin Dry Cow is a sterile suspension of cloxacillin as the benzathine salt in a long acting mineral oil base, presented in syringes containing 500 mg cloxacillin as cloxacillin benzathine in 3 g of suspension.

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

120 syringes

5. TARGET SPECIES

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6. INDICATION(S)

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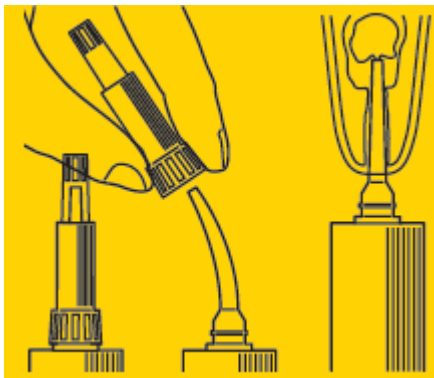
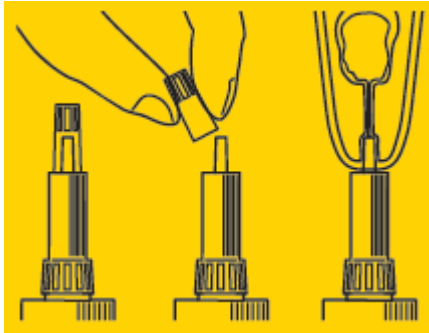
7. METHOD AND ROUTE(S) OF ADMINISTRATION

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 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

Not intended for use within 30 days of calving.

Milk for human consumption may only be taken from 204 hours after calving.

Should a cow calve earlier than 30 days after treatment, milk for human consumption may only be taken after 30 days plus 204 hours from 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 lactating cows are accidentally infused, milk should be withheld from the bulk supply for 30 days or less if testing shows it to be free from antibiotic residues.

WARNING: 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

Expires end:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Keep the syringes in the outer carton.

The syringe must 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

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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 42058/4088

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™ Dry Cow 500 mg Intramammary Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 3 g syringe contains 500 mg of cloxacillin as Cloxacillin benzathine.

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

3 g

4. ROUTE(S) OF ADMINISTRATION

For single use only.

5. WITHDRAWAL PERIOD

Meat: 28 days. Milk: 30 days plus 204 hours.

See package leaflet for full details

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expires end:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep out of sight and reach of children.

Do not store above 25°C.

Vm 42058/4088

POM-V

To be supplied only on veterinary prescription.

Penicillins/cephalosporins may cause 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™ Dry Cow 500 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™ Dry Cow 500 mg Intramammary Suspension

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

Orbenin Dry Cow is a sterile suspension of cloxacillin as the benzathine salt in a long acting mineral oil base, presented in syringes containing 500 mg cloxacillin as cloxacillin benzathine in 3 g of suspension.

The active material is a semi-synthetic penicillin derived from the penicillin nucleus, 6-aminopenicillanic acid.

It is presented in 4.5 ml syringes for intramammary infusion and is designed to be used in the dairy cow at the point of drying off, that is immediately after the last milking of the lactation.

The combined effects of the relatively insoluble benzathine salt and the long acting base give an extended period of activity for 3-4 weeks in the dry cow. The preparation is not suitable for treatment of the lactating cow, since its persistence would involve discarding milk with antibiotic residues over a prolonged period.

4. INDICATIONS

Mastitis caused by streptococci is still common, but staphylococci, many strains of which are penicillin resistant, now account for a large proportion of cases. The extent of sub-clinical and latent infections in a herd is frequently unsuspected, but up to half the herd may well be affected, although a much smaller number show clinical signs at any one time. In untreated herds a significant build up of sub-clinical infection can occur during the dry period, so that after a number of lactations the incidence of infection becomes serious.

The influence of sub-clinical infection on milk yield, the risk of cross-infection and the chance of clinical infections flaring up, make it necessary to treat the matter as a herd problem.

While no single form of treatment will be likely to eliminate mastitis entirely, extensive investigations have proved the value of treating all the cows in the herd as they are dried off, with Orbenin in the Dry Cow formulation. The cow is milked out for the last time and one syringe of Orbenin Dry Cow is infused into each quarter and left. It is desirable to use an antiseptic teat dip and other routine hygienic measures to help maintain the control of infection in the herd.

While cases of mastitis, if they arise during lactation, will still require treatment with an appropriate antibiotic, the use of routine dry cow medication has been shown to achieve very valuable control of herd infections and a large majority of staphylococcal infections due to penicillin-resistant as well as sensitive organisms. Since the treatment is during the dry period it does not lead to loss from discarded milk.

Orbenin is active against Gram-positive organisms associated with mastitis. It is highly effective against *Streptococcus agalactiae* and other streptococcal species, penicillin-resistant and sensitive staphylococci and *Arcanobacterium pyogenes*. Unlike natural penicillins, Orbenin is not destroyed by staphylococcal penicillinase. It is therefore active against penicillin-resistant staphylococci which are an important cause of mastitis.

The benzathine salt of Orbenin retains its activity over a considerable period and, in the long-acting aluminium stearate base, maintains effective antibacterial levels in the mammary gland of the dry cow for approximately three to four weeks.

The antibiotic is bactericidal, causing the death of organisms at the concentrations produced and it is non-irritant in the udder tissues.

5. CONTRAINDICATIONS

Do not use in the lactating cow.

6. ADVERSE REACTIONS

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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 the end of lactation milk the cow out normally. Clean and disinfect the teat, infuse one syringe of Orbenin Dry Cow into each quarter and leave it, without milking out. It is normally unnecessary and undesirable to introduce any further treatment during the dry period.

10. WITHDRAWAL PERIODS

Not intended for use within 30 days of calving. Milk for human consumption may only be taken from 204 hours after calving. Should a cow calve earlier than 30 days after treatment, milk for human consumption may only be taken after 30 days plus 204 hours after last treatment, consult your veterinary surgeon.

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 sight and reach of children.

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

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 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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Orbenin Dry Cow is supplied in cartons of 24, 60 or 120 syringes. Not all pack sizes may be marketed.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4088

Product Summary

- Orbenin Dry Cow is specially prepared for treatment of the dry cow.
- It maintains effective antibiotic levels in the udder for a period of weeks and is non-irritant.
- It is bactericidal with activity against penicillin-resistant and sensitive staphylococci, streptococci and *Arcanobacterium pyogenes*.
- Treatment during the dry period avoids financial loss from discarded milk.

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Approved 04 September 2020

