PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Ophthalmic Ointment 16.67% w/w Eye Ointment

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 3g tube contains 500mg of cloxacillin (16.67% w/w) as cloxacillin benzathine in a non-irritant ophthalmic base.

3. PHARMACEUTICAL FORM

Eye ointment

4. PACKAGE SIZE

12 tubes

5. TARGET SPECIES

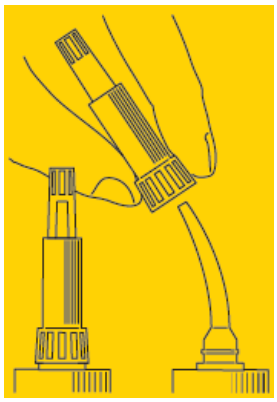
Cattle, sheep, horses, dogs and cats

6. INDICATION(S)

Uses: Orbenin Ophthalmic Ointment is effective against a wide range of bacteria (including Moraxella spp.) commonly isolated from the eyes of domestic animals i.e. cats, dogs, sheep, horses, cattle. It is particularly useful for treating New Forest Eye in cattle and Contagious Ophthalmia ("Pink Eye") in sheep.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: For topical application to the eye. For full details see package leaflet.



8. WITHDRAWAL PERIODS

Milk: Cattle and sheep – Zero hours.

Meat: Cattle, sheep and horses – Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

For external use only

For full details on warnings, precautions and disposal advice see package leaflet.

User warnings:

Penicillins may occasionally cause severe allergic reactions.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Any contents remaining 28 days after tube was first opened should be discarded.

Care should be taken to avoid contamination of contents during use.

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

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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 Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 60021/3090

17. MANUFACTURER'S BATCH NUMBER

Batch No:

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Ophthalmic Ointment 16.67% w/w Eye Ointment

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 3 g tube contains 500mg of cloxacillin (16.67% w/w) as Cloxacillin benzathine in a non-irritant ophthalmic base.

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

3 g

4. ROUTE(S) OF ADMINISTRATION

Dosage: For topical application to the eye. For full details see enclosed leaflet.

5. WITHDRAWAL PERIOD

Meat & milk – Zero days.

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

User warnings: See package leaflet.

For animal treatment only.

Keep out of the sight and reach of children.

For external use only.

Do not store above 25°C.

Vm 60021/3090

POM-V

To be supplied only on veterinary prescription.

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

PACKAGE LEAFLET FOR:

Orbenin™ Ophthalmic Ointment 16.67% w/w Eye Ointment

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
Dublin 18
D18 T3Y1
Ireland
Batch release site not listed

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin™ Ophthalmic Ointment 16.67% w/w Eye Ointment

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

Orbenin Ophthalmic Ointment is an off-white, stable suspension of Cloxacillin benzathine in a non-irritant ophthalmic base with 3% aluminium stearate. It is prepared under sterile conditions, and is presented as tubes containing 500mg cloxacillin (16.67% w/w) as the benzathine salt, in 3g of suspension.

4. INDICATIONS

Orbenin Ophthalmic Ointment is effective against a range of bacteria (including Moraxella spp.) commonly isolated from the eyes of domestic animals. It is bactericidal in action and its formulation facilitates persistence of effective cloxacillin levels following a single application.

The product is indicated for the treatment of ocular infections in cattle, sheep, horses, dogs and cats where susceptible organisms (including *Moraxella* spp.) are suspected or anticipated as pathogens. A particular indication is the treatment of New Forest Eye in cattle.

5. CONTRAINDICATIONS

For external use only.

6. ADVERSE REACTIONS

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7. TARGET SPECIES

Cattle, sheep, horses, dogs and cats.

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

For topical administration only.

Evert the lower eyelid and instil the ointment liberally into the lower conjunctival sac (e.g. approximately 1/4 to 1/2 tube per eye in cattle and horses, 1/4 tube per eye in sheep and 1/10 of a tube per eye in dogs and cats).

For the treatment of New Forest Eye in cattle and Contagious Ophthalmia (“Pink Eye’’) in sheep, one application only is normally required; but treatment may be repeated at intervals of 48 hours in cattle and 72 hours in sheep if necessary.

9. ADVICE ON CORRECT ADMINISTRATION

In practice, dogs, cats and horses with ocular infections are examined on a relatively frequent basis.

Treatment should be repeated at 24 hourly intervals in dogs, cats and horses. If the animal only has one eye infected, it may be advisable to treat both eyes to prevent cross infection. In such cases, it is better to treat the uninfected eye first to avoid transferring infection via the tube nozzle.

10. WITHDRAWAL PERIODS

Animals must be not be slaughtered for human consumption during treatment. Cattle, sheep and horses may only be slaughtered for human consumption after last treatment.

Milk withdrawal period: Cattle and sheep - Zero hours.

Meat withdrawal period: Cattle, sheep and horses - Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Keep out of the sight and reach of children.

Care should be taken to avoid contamination of the contents during use. Any contents remaining 28 days after the tube was first opened should 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 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 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 Ophthalmic Ointment is supplied in boxes containing 12 tubes.

The consistency of Orbenin Ophthalmic Ointment ensures even distribution of ointment across the cornea and the conjunctival mucosae. Effective cloxacillin levels are maintained for sufficient time, after only one application, to effect a cure in the majority of cases of New Forest Eye and Contagious Ophthalmia. Treatment of a batch of "in-contact" cattle or sheep at the time clinical signs first appear in some individuals may reduce the overall severity of outbreaks of ocular disease on a herd/flock basis.

POM-V

To be supplied only on veterinary prescription.
Vm 60021/3090

Product Summary

Persistent Antibiotic Levels - the special long acting base maintains cloxacillin levels on the eye surface following a single application.

Clinical Efficacy - demonstrated by clinical trials in cattle, sheep, horses, dogs and cats.

Effective against *Moraxella* spp. - indicated for the treatment of New Forest Eye in cattle. A single dose is usually sufficient.

Appropriate Formulation - ointment is easy to apply and disperses well following application.

Special tube - short rounded nozzle particularly suitable for ophthalmic use.

Gavin Hall

Approved: 20 May 2025