

RECEIVED

By J Webb E-Labels at 10:08 am, Aug 10, 2010

PFIZER ANIMAL HEALTH

Product Name: ORBENIN [®] EYE OINTMENT	
Date: 9 August 2010	Page 1 of 1
Product Size: 3g	Description: Immediate Label
File number: 35893_50037_3g_immediate_MPL_V01.doc	Version: May 2010

Text above this line and in italics between parallel lines is not included in the label copy.

IMMEDIATE CONTAINER – Syringe Label

**PRESCRIPTION ANIMAL REMEDY
FOR ANIMAL TREATMENT ONLY**

ORBENIN[®] EYE OINTMENT

Each syringe contains
500 mg CLOXACILLIN
as Benzathine Salt
3g

For the treatment of cloxacillin susceptible
bacterial keratoconjunctivitis
in cattle, sheep, horses, dogs and cats.

READ ENCLOSED LEAFLET BEFORE USE

WITHHOLDING PERIOD: NIL

TRADE ADVICE: ESI: Not Established

P.A.R CLASS 1 ACVM NO. A4751

APVMA No.: 35893/50037

STORE below 25°C (Air Conditioning)



® Registered Trademark ® 2010

Batch No:

Exp:

BARCODE



**RLP
Approved**



RECEIVED

By J Webb E-Labels at 10:07 am, Aug 10, 2010

PFIZER ANIMAL HEALTH

Product Name: ORBENIN [®] EYE OINTMENT	
Date: 9 August 2010	Page 1 of 2
Product Size: 20 x 3g, 24 x 3g	Description: Leaflet
File number: 35893_50037_leaflet_MPL_V01.doc	Version: May 2010

Text above this line and in italics between parallel lines is not included in the label copy.

LEAFLET

PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

ORBENIN[®]
EYE OINTMENT

BARCODE

**PRESENTATION**

Orbenin Eye Ointment is an off-white, stable suspension of Cloxacillin Benzathine B.P. (Vet) in a non-irritant ophthalmic base. It is a sterilised product, presented in syringes containing 500 mg cloxacillin as the benzathine salt, in 3g of suspension.

INDICATIONS

Orbenin Eye Ointment is indicated for the treatment of bovine keratoconjunctivitis caused by cloxacillin susceptible bacteria including *Moraxella bovis*. Also for the treatment of keratoconjunctivitis caused by cloxacillin susceptible bacteria in sheep, horses, dogs and cats.

This product is effective against a range of bacteria commonly isolated from the eyes of cattle, sheep, horses, dogs and cats. It is not effective against *Pseudomonas*, *Mycoplasma* or *Chlamydia* spp. It is bactericidal in action and its formulation facilitates persistence of cloxacillin levels for at least 48 hours following a single application.

DIRECTIONS FOR USE

This product is contraindicated for use in animals with a history of allergic reaction to penicillins.

Warning: People allergic to penicillins should wear gloves when administering the treatment.

Dosage and Administration

For topical administration only.

Evert the animal's lower eyelid and instill the ointment liberally into the lower conjunctival sac. Do not allow the plastic nozzle to directly contact the eye (corneal) surface. The consistency of Orbenin Eye Ointment ensures even distribution of ointment across the cornea and the conjunctival mucosa.

Product Name: ORBENIN® EYE OINTMENT	
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Cattle, Sheep and Horses: Approximately ¼ to ½ contents of syringe per eye. One application only per eye is normally required but treatment may be repeated at 48 hour intervals if necessary.

If the animal has only one eye infected it is advisable to treat both eyes to avoid cross infection. Always treat the uninfected eye first.

Animals should be examined for the presence of foreign bodies in the eye before treatment with Orbenin Eye Ointment.

Isolation and treatment of all animals in the group with epiphora, at the time clinical signs first appear in some individuals, may reduce the overall severity of epidemics of keratoconjunctivitis on a herd basis.

Fly control and avoiding dusty conditions or long grass will reduce the incidence of eye infections.

Dogs and Cats: Instill into the affected eye as directed by your veterinarian.

WITHHOLDING PERIOD NIL

TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): This product does not have an ESI established. For advice on the ESI, contact the manufacturer on 1800 814 883 before using this product.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. *Phone Australia 131126; New Zealand 0800 764 766.*

Prescription Animal Remedy (P.A.R) Class I
For use only following a veterinary consultation

Registered pursuant to the ACVM Act 1997, No A4751
 See www.nzfsa.govt.nz/acvm/ for registrations conditions

APVMA Approval Number: 35893/~~50037~~ 50037

STORAGE

Store below 25°C (Air Conditioning)

DISPOSAL

Dispose of empty container by wrapping with paper and putting in garbage.

PRESENTATION

Orbenin Eye Ointment is supplied in cartons, containing 20 [24] syringes.



Made in Italy
 Animal Health
 A division of Pfizer Australia Pty Ltd
 38-42 Wharf Rd, West Ryde, NSW, 2114, Australia
 Pfizer Laboratories Ltd
 Normanby Rd, Mt Eden, Auckland, New Zealand

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By J Webb E-Labels at 10:09 am, Aug 10, 2010

PFIZER ANIMAL HEALTH

Product Name: ORBENIN [®] EYE OINTMENT	
Date: 9 August 2010	Page 1 of 3
Product Size: 24 x 3g	Description: Primary Label
File number: 35893_50037_24_primary_MPL_V01.doc	Version: May 2010

Text above this line and in italics between parallel lines is not included in the label copy.

PRIMARY PACK – Front Panel

PRESCRIPTION ANIMAL REMEDY
KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY

ORBENIN[®]
EYE OINTMENT

Each 3g syringe contains
500 mg CLOXACILLIN as Benzathine Salt

For the treatment of bovine keratoconjunctivitis
caused by cloxacillin susceptible bacteria
including *Moraxella bovie*.

Also for the treatment of keratoconjunctivitis caused by cloxacillin susceptible bacteria
in sheep, horses, dogs and cats.

24 syringes each 3g



Product Name: ORBENIN [®] EYE OINTMENT	
Date: 9 August 2010	Page 2 of 3
Product Size: 24 x 3g	Description: Primary Label
File number: 35893_50037_24_primary_MPL_V01.doc	Version: May 2010

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PRIMARY PACK – Back Panel

ORBENIN[®] EYE OINTMENT

Orbenin Eye Ointment is effective against a range of bacteria commonly isolated from the eyes of cattle, sheep, horses, dogs and cats. It is not effective against *Pseudomonas*, *Mycoplasma* or *Chlamydia* spp.

It is bactericidal in action and its formulation facilitates persistence of cloxacillin levels for at least 48 hours following a single application. Orbenin Eye Ointment is indicated for the treatment of keratoconjunctivitis where cloxacillin susceptible bacteria (including *Moraxella bovis*) are suspected or anticipated as pathogens.

READ ENCLOSED LEAFLET BEFORE USING THIS PRODUCT

DIRECTIONS FOR USE

This product is contraindicated for use in animals with a history of allergic reaction to penicillins.

Warning: People allergic to penicillins should wear gloves when administering the treatment.

Dosage and Administration

For topical use only. Instill liberally into the lower conjunctival sac of the affected eye.

Cattle and Horses: One quarter to half of the contents of one syringe. One application only, per eye, is normally necessary, but treatment may be repeated at 48 hour intervals if required.

Dogs and Cats: Instill into the affected eye as directed by your veterinarian.

WITHHOLDING PERIOD NIL

TRADE ADVICE

EXPORT SLAUGHTER INTERVAL (ESI): This product does not have an ESI established. For advice on the ESI, contact the manufacturer on 1800 814 883 before using this product.

FIRST AID: If poisoning occurs, contact a doctor or Poisons Information Centre. *Phone Australia 131126; New Zealand 0800 764 766.*

DISPOSAL: Dispose of empty containers by wrapping with paper and putting in garbage.

BARCODE



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PRIMARY PACK – Top Panel

ORBENIN[®] EYE OINTMENT

24 syringes



PRIMARY PACK – Base Panel

ORBENIN[®] EYE OINTMENT

Batch:

Exp:

Store below 25°C (Air Conditioning)

Prescription Animal Remedy (P.A.R) Class 1
For use only following a veterinary consultation

Registered pursuant to the ACVM Act 1997, No. A4751

APVMA Approval Number: 35893/ 50037

Made in Italy

Pfizer Animal Health

A division of Pfizer Australia Pty Ltd

38-42 Wharf Rd West Ryde NSW 2114 Australia

Pfizer Laboratories Ltd

Normanby Rd, Mt Eden, Auckland, New Zealand

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PRIMARY PACK – Left & Right Side Panels

ORBENIN[®] EYE OINTMENT

For the treatment of cloxacillin susceptible bacterial
keratoconjunctivitis in cattle, sheep, horses, dogs and cats.

24 syringes