

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

OPTICLOX EYE OINTMENT 16.7% w/w

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Each 5 g syringe contains 16.7% w/w cloxacillin (as cloxacillin benzathine 21.3% w/w)

### **3. PHARMACEUTICAL FORM**

Eye ointment.

### **4. PACKAGE SIZE**

Opticlox Eye Ointment is supplied in cartons of 4 x 5 g syringes.

### **5. TARGET SPECIES**

Horses  
Cattle  
Sheep  
Dogs  
Cats

### **6. INDICATION(S)**

Opticlox Eye Ointment is indicated for the treatment of eye infections in cattle, sheep, horses, dogs and cats caused by *Staphylococcus* spp and *Bacillus* spp.

### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For topical administration only.

Evert the lower eyelid and instill a steady flow of ointment into the lower conjunctival sac. Normally a single application only is required, but treatment may be repeated after 48 - 72 hours if necessary. Wherever possible, Opticlox Eye Ointment should only be used based on susceptibility testing.

#### Dosage guide:

Cattle and Horses: approximately 5 - 10 cm of ointment per eye.  
Sheep: approximately 5 cm of ointment per eye.  
Dogs and Cats: approximately 2 cm of ointment per eye.

For animals with only a single infected eye it is recommended, to prevent cross infection, that both eyes be treated, treating the uninfected eye first to avoid transferring the infection. Each syringe to be used once only.

## **8. WITHDRAWAL PERIOD**

Cattle and Sheep (Milk): Zero hours.

Cattle, Sheep and Horses (Meat): Zero days.

## **9. SPECIAL WARNING(S), IF NECESSARY**

### **Operator warning - Penicillin/Cephalosporin sensitivity:**

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.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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: dd/mm/yyyy

## **11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Each syringe should be used on one occasion only.

Unused ointment should be discarded after treatment.

Keep container in outer carton

## **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

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

**KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**Manufactured by:**

Norbrook Laboratories Limited  
Station Works  
Newry  
Co. Down, BT35 6JP

**Distributed by:**

Norbrook Laboratories Limited  
Carnbane Industrial Estate  
Newry  
Co. Down  
BT35 6QQ  
Northern Ireland

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 02000/4075  
ManA 2000

**17. MANUFACTURER’S BATCH NUMBER**

B.N.:  
DOM:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

OPTICLOX EYE OINTMENT 16.7% w/w

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

5g

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

Cloxacillin (as cloxacillin benzathine 21.3% w/w) 16.7% w/w, equivalent to 835 mg cloxacillin in a long acting base.

**4. ROUTE(S) OF ADMINISTRATION**

For topical administration to horses, cattle, sheep, dogs and cats. Evert the lower eyelid and instil a steady flow of ointment across the lower conjunctival sac. Keep container in outer carton.

**Dosage guide:**

Cattle and Horses: approx 5-10cm of ointment per eye.

Sheep: approx 5cm of ointment per eye

Dogs and cats: approx 2cm of ointment per eye

Each syringe should be used on one occasion only. Unused ointment should be discarded after treatment.

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See carton for full user warnings.

**5. WITHDRAWAL PERIOD**

**Milk:** Zero hours **Meat:** Zero days

**6. BATCH NUMBER**

BN:

**7. EXPIRY DATE**

Exp: dd/mm/yyyy

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

**FOR ANIMAL TREATMENT ONLY**

POM-V

To be supplied only on veterinary prescription.

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET**

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

Norbrook Laboratories Limited  
Station Works  
Newry  
Co. Down, BT35 6JP

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

OPTICLOX EYE OINTMENT 16.7% w/w

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

Each 5 g syringe contains 16.7% w/w cloxacillin (as cloxacillin benzathine 21.3% w/w)

**4. PHARMACEUTICAL FORM**

Eye ointment.

**5. PACKAGE SIZE**

Opticlox Eye Ointment is supplied in cartons of 4 x 5 g syringes.

**6. INDICATION(S)**

Opticlox Eye Ointment is indicated for the treatment of eye infections in cattle, sheep, horses, dogs and cats caused by *Staphylococcus* spp and *Bacillus* spp.

**7. CONTRAINDICATIONS**

**8. ADVERSE REACTIONS**

**9. TARGET SPECIES**

Horses  
Cattle  
Sheep  
Dogs  
Cats

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

For topical administration only.

Evert the lower eyelid and instill a steady flow of ointment into the lower conjunctival sac. Normally a single application only is required, but treatment may be repeated after 48 - 72 hours if necessary. Wherever possible, Opticlox Eye Ointment should only be used based on susceptibility testing.

Dosage guide:

Cattle and Horses: approximately 5 - 10 cm of ointment per eye.  
Sheep: approximately 5 cm of ointment per eye.  
Dogs and Cats: approximately 2 cm of ointment per eye.

For animals with only a single infected eye it is recommended, to prevent cross infection, that both eyes be treated, treating the uninfected eye first to avoid transferring the infection. Each syringe to be used once only.

**11. ADVICE ON CORRECT ADMINISTRATION**

**12. WITHDRAWAL PERIOD**

Cattle and Sheep (Milk): Zero hours.  
Cattle, Sheep and Horses (Meat): Zero days.

**13. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25°C. Each syringe should be used on one occasion only.  
Unused ointment should be discarded after treatment.  
Keep container in outer carton

**14. SPECIAL WARNING(S)<User Warnings>**

**Operator warning - Penicillin/Cephalosporin sensitivity:**

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.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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.

## 15. EXPIRY DATE

Exp: dd/mm/yyyy

## 16. SPECIAL 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.

## 17. DATE ON WHICH THE LABEL WAS LAST APPROVED

*[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included:]*

<Find more product information by searching for the Product Information Database 'PID' on [www.gov.uk](http://www.gov.uk).>

## 18. 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.

## 19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

### KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

## 20. MARKETING AUTHORISATION NUMBER(S)

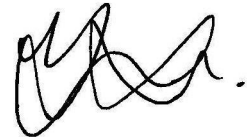
Vm 02000/4075  
ManA 2000

## 21. MANUFACTURER'S BATCH NUMBER

## 22. OTHER INFORMATION

**Manufactured by:**  
Norbrook Laboratories Limited  
Newry, B  
T35 6JP

**Distributed by:**  
Norbrook Laboratories Limited  
Carnbane Industrial Estate  
Newry  
Co. Down  
BT35 6QQ  
Northern Ireland

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 28 October 2022