

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Opticlox Eye Ointment 16.7% w/w.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each 5 g syringe contains 16.7% w/w Cloxacillin (as cloxacillin benzathine 21.3% w/w) equivalent to 835 mg cloxacillin.

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye ointment.

A smooth sterile cream for ophthalmic use.

4. CLINICAL PARTICULARS

4.1 Target species

Horses
Cattle
Sheep
Dogs
Cats

4.2 Indications for use, specifying the target species

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.

4.3 Contra-indications

None, according to available data.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

For external use only.

Wherever possible, Opticlox Eye Ointment should only be used based on susceptibility testing.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Operator warning - penicillin/cephalosporin sensitivity:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following, 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 skin rash you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None, according to available data.

4.7 Use during pregnancy, lactation or lay

Opticlox Eye Ointment can be safely administered to pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No treatment specified.

4.11 Withdrawal period

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibiotics

ATC Vet Code: QS01AA90

5.1 Pharmacodynamic properties

Cloxacillin is active against Penicillin G resistant staphylococci. It binds to membrane bound proteins known as Penicillin-binding proteins (PBP's).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Stearate
Liquid Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

A white low-density polyethylene syringe with a snap on cap containing 5g of a smooth sterile cream.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4075

9. DATE OF FIRST AUTHORISATION

17th December 1986.

10. DATE OF REVISION OF THE TEXT

19th November 2008.