1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Opticlox Eye Ointment 167 mg/g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g syringe contains:

Active substance(s):

167 mg/g Cloxacillin (as benzathine salt) equivalent to 835 mg cloxacillin, in a long-acting base.

Excipient(s):

Qualitative composition of excipients and other constituents
Liquid Paraffin
Aluminium Stearate

A smooth off-white cream.

3. CLINICAL INFORMATION

3.1 Target Species

Horses, cattle, sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of eye infections in cattle, sheep and horses caused by *Staphylococcus* spp. and *Bacillus* spp.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances can occasionally be serious.

1. People with known hypersensitivity to penicillin and cephalosporins should avoid contact with the veterinary medicinal product.

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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For topical administration only.

Evert the lower eyelid and instil 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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.
Milk: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code : QS01AA90

4.2 Pharmacodynamics

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

White low density polyethylene syringe with a white low density polyethylene snap-on cap containing 5 g of product. Pack sizes 4 x 5 g syringes packed into a carton.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/007/001

8. DATE OF THE FIRST AUTHORISATION

01/10/1987

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

24/06/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).