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 benzathine salt) equivalent to 835 mg cloxacillin, in a long-acting base.

Excipients:

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Eye ointment.
Off-white ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, Cattle, Sheep

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

No special warnings.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special Precautions to be taken by the Person Administering the 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. 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 and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

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 interactions

None known.

4.9 Amounts to be administered and administration route

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.

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

Not applicable.

4.11 Withdrawal period(s)

Meat/milk - Nil

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group : Antibacterial ATCvet 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

Liquid Paraffin
Aluminium Stearate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Unused ointment should be discarded after treatment.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 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.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1987
Date of last renewal: 30 September 2007

10 DATE OF REVISION OF THE TEXT

January 2019