**IRISH MEDICINES BOARD ACT 1995**

**ANIMAL REMEDIES REGULATIONS, 2005**

**(S.I. No. 734 of 2005)**

VPA: **10019/028/001**
Case No: 7002035

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

**Pfizer Healthcare Ireland**

**Trading as Pfizer Animal Health**, **Ringaskiddy**, **Co. Cork**, **Ireland**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Orbenin Ophthalmic Ointment 500mg**

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin Ophthalmic Ointment 500 mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3g tube contains:
Active Substance

| | |
|---|---|
| Cloxacillin (as cloxacillin benzathine) | 500mg |

Excipients

| | |
|---|---|
| Mineral oil base to | 3g |

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye ointment

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, sheep, horses, dogs and cats.

### 4.2 Indications for use, specifying the target species

For the treatment of ocular infections in cattle, sheep, horses, dogs and cats where susceptible organisms, such as *Staphylococcus aureus* (including b-lactamase producing strains), *Moraxella bovis* and *Branhamella ovis*, are suspected or anticipated as pathogens. A particular indication is treatment of New Forest Disease in cattle.

### 4.3 Contraindications

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

### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

**Special precautions for use**

None.

**Special Precautions to be taken by the Person Administering the Medicinal Product to Animals**

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

Orbenin Ophthalmic Ointment may be used safely in both 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 application only. The syringe has a nozzle adaptor but it is recommended that the short nozzle is used.
The short nozzle is selected as follows:
Hold top section of the white cap between forefingers and thumb. Bend top of cap and break to remove. Do not touch the nozzle with fingers.
Evert the lower eyelid and instil the ointment liberally into the lower conjunctival sac, for example:
Cattle and horses: ¼ - ½ syringe per eye
Sheep: ¼ syringe per eye
Dogs and cats: $^{1}/_{10}$ syringe per eye
If the animal only has one infected eye, it may be advisable to treat both eyes to prevent cross infection. In such cases it is better to treat the un-infected eye first to avoid transferring infection via the tube nozzle.
For treatment of New Forest Disease in cattle and contagious ophthalmia in sheep one application only is normally required, but treatment may be repeated at intervals of 48 hours in cattle and 72 hours in sheep if necessary.
Treatment should be repeated at 24 hourly intervals in dogs, cats and horses.

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

Orbenin is very well tolerated by the target species and has proved safe in use.
Accidental overdose is unlikely to cause any adverse side effects.

## 4.11 Withdrawal Period(s)

Animals must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after the last treatment. Sheep and horses may be slaughtered for human consumption after 4 days from the last treatment.
Milk withdrawal period in cattle and sheep : nil.

# 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Cloxacillin is a beta-lactam antibiotic which interferes with cell wall synthesis and is thus bactericidal. It is not destroyed by staphylococcal ß-lactamase **and** is therefore active against penicillin-resistant staphylococci. The formation facilitates the persistence of effective cloxacillin levels following a single application. The consistency of the ointment ensures its even distribution across the cornea and the conjunctival mucosae.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Mineral Base qs ad

The mineral base has the following formulation:

Stearic acid B.P.
Aluminium stearate
Liquid Paraffin

## 6.2 Incompatibilities

None known.

## 6.3 Shelf-life

48 months.

Any contents remaining 28 days after the date on which the container was first opened, should be discarded.

## 6.4 Special precautions for storage

Do not store above 25$^{o}$C.

## 6.5 Nature and composition of immediate packaging

3gms of sterile off-white viscous suspension of eye ointment contained in low density polyethylene tubes.

Boxes containing 12 tubes.

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Pfizer Healthcare Ireland,
Trading as:
Pfizer Animal Health,
Ringaskiddy,
County Cork,
Ireland.

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/28/1

## 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002