SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin Ophthalmic Ointment 16.67% w/w Eye Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	**g/tube**
Cloxacillin (as cloxacillin benzathine)	0.5g

Other ingredients	
Mineral oil base to	3.0g

For the full list of all other 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 beta-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

None.

4.4 Special warnings for each target species

For external use only.

4.5 Special precautions for use

(i) Special precautions for use in animals

Care should be taken to avoid contamination of the contents during use.

(ii) Special precautions to be taken by the person administering the veterinary 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 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

The product 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 tube 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 $^1/_4$ - $^1/_2$ tube per eye.
Sheep $^1/_4$ tube per eye.
Dogs and cats $^1/_{10}$ tube per eye.

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.

Even if only one eye is affected, it may be advisable to treat both eyes; the unaffected eye first to avoid transmitting the infection.

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

The product 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 periods

Animals must not be slaughtered for human consumption during treatment. Cattle, sheep and horses may be slaughtered for human consumption only after the last treatment.

Milk: Cattle and sheep: Zero hours.
Meat: Cattle, sheep and horses: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Cloxacillin is a beta-lactam antibiotic which is bactericidal in action by interfering with cell wall synthesis. It is not destroyed by staphylococcal β-lactamase and is therefore active against penicillin-resistant staphylococci. The formulation 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.

ATC Vet code: QS01AA90

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic Acid
Aluminium Stearate
Liquid Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.

Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25˚C.

Any contents remaining 28 days after the tube was first opened should be discarded.

6.5 Nature and composition of immediate packaging

A sterile off white viscous suspension of eye ointment contained in 3g low density polyethylene tubes. Boxes contain 12 tubes.

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

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

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 60021/3090

9. DATE OF THE FIRST AUTHORISATION

14 September 1990

10. DATE OF REVISION OF THE TEXT

May 2025

Gavin Hall
Approved: 20 May 2025