1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin Dry Cow 500 mg intramammary suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3g intramammary syringe contains:

Active substance:
Cloxacillin (as cloxacillin benzathine) 500 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Mineral oil base to	3 g
Stearic Acid	
Aluminium stearate	
Liquid Paraffin	

Sterile off-white hydrophobic intramammary suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the infusion of cows at drying off, to treat mastitis infections and to provide protection against further infections during the dry period.

3.3 Contraindications

Do not use in the lactating cow.

In common with other penicillins, cloxacillin should not be used orally or parenterally in rabbits, guinea-pigs, hamsters or gerbils. Caution is advised in its use in other very small herbivores.

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:

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 reaction 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 package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent attention.

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 also last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Lactation:
Not for use in lactating cows. Not intended for use within 35 days of calving.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

One syringe per quarter immediately after the final milking of lactation. At drying off clean and disinfect the teat following the last milking, insert nozzle into the teat and apply gentle and continuous pressure until the suspension is expressed.

Care should be taken to avoid contamination of the injector nozzle. Following infusion, it is advisable to use a teat dip or spray.

Each syringe may only be used once.

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: 28 days.
Milk: 96 hours after calving.

Not intended for use within 35 days of calving. Milk for human consumption may only be taken from 96 hours after calving (that is, at the 8th milking in cows milked twice daily). If calving occurs before 35 days after last treatment, milk for human consumption may only be taken after 35 days plus 96 hours after last treatment.

If lactating cows are accidentally infused, milk should be withheld from the bulk supply for 35 days, or less time if testing shows it to be free from antibiotic residues.

4. PHARMACOLOGICALINFORMATION

4.1 ATCvet code: QJ51CF02 cloxacillin

4.2 Pharmacodynamics

The product is active against Gram-positive organisms associated with mastitis. It is effective against *Streptococcus agalactiae* and other streptococcal species, staphylococci (penicillin resistant and sensitive strains) and *Corynebacterium pyogenes*.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 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 intramammary syringe barrel containing 3 g of suspension with plunger. The closure is a white low density polyethylene push-fit combined dual nozzle and cap.

Packs containing 24 or 120 syringes.

Not all pack sizes may be marketed.

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

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/045/001

8. DATE OF FIRST AUTHORISATION

01 October 1997

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

23 November 2023

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*).