Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin Dry Cow 500 mg Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3g dose unit 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

Sterile off-white hydrophobic intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

Do not use in the lactating cow. 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. In common with other penicillins, cloxicillin 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 animals with known sensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

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 doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and may require urgent attention.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

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

Not applicable.

4.11 Withdrawal Period(s)

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 8^{th} 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. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered only after 28 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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*.

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.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 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.

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

Zoetis Belgium S.A
2nd Floor, Building 10
Cherrywood Business Park
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10387/045/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1997
Renewal of the last authorisation: 1st October 2007

10 DATE OF REVISION OF THE TEXT

March 2017