1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbenin Extra Dry Cow 600 mg Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3.6g syringe contains

Active Substance
Cloxacillin (as Cloxacillin Benzathine)600mg

Excipients

Mineral oil base to 3.6g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.
A white to off-white viscous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in the lactating cow. If a lactating cow is accidentally infused, milk should be withheld from the bulk supply for 46 days or less time if testing shows the level of cloxacillin in the milk to be within the WHO tolerance limit of 0.02 µg/ml (ppm).

In common with all 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 animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use

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 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 medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not for use in lactating cows.
Do not use in dairy cows within 42 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 to be infused per quarter immediately after cleaning and disinfecting the teats following the last milking before drying off. Care should be taken to avoid contamination of the injector nozzle. After infusion it is advisable to dip each teat in a licensed teat dip.The 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 in cows with dry periods of 42 days or less. Milk for human consumption may only be taken from 96 hours (that is, at the 8thmilking in cows milked twice daily) after calving. If calving occurs before 42 days after last treatment, milk for human consumption may only be taken from 42 days plus 96 hours after the last treatment.

Cattle must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption 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, Streptococcus dysgalactiae*, *Streptococcus uberis*, penicillin-resistant and penicillin-sensitive staphylococci and *Actinomyces pyogenes*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic Acid
Aluminium StearateLiquid Paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 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 syringes containing 3.6 g of a sterile white hydrophobic suspension for intramammary infusion.
The closure is a white low density polyethylene push-fit combined dual nozzle and cap. For single-use only.
Cartons containing 24 and 120 (2 x 60) syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/046/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1997
Date of last renewal: 30th September 2007

10 DATE OF REVISION OF THE TEXT

September 2017