Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zeromast 600 mg/syringe Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Cloxacillin 600 mg / syringe
(as Cloxacillin Benzathine)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cow.

4.2 Indications for use, specifying the target species

Zeromast is intended for the control and prevention of mastitis during lactation in cows.
The great majority of bacteria which cause mastitis in lactating cows are *Staphylococcus* and *Streptococcus* species and in some instances *Actinomyces pyogenes*. Most of these are sensitive to Cloxacillin.

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 in animals
The treatment should be given when clinical mastitis is diagnosed, following complete removal of all the contents of the affected quarter. All the secretion should be removed at next milking. Ensure the teat end has been disinfected prior to infusion. When the cap has been removed from the syringe, care should be taken to avoid contamination of the nozzle.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Operators should avoid contact with this preparation as occasionally skin allergy may occur.

Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact. Sensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know that you are sensitised or if you have been advised not to work with such preparations.

If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Zeromast is intended for use in cows during the lactation. It has no adverse effects on pregnancy or the conceptus.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For intramammary infusion in lactating cows only. All affected quarters should be infused. The teat should be cleansed and disinfected prior to infusion.
Administer one tube per infected quarter once.

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

Not applicable.

4.11 Withdrawal period(s)

(a) Meat
Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered only after 7 days from the last treatment.

(b) Milk
Milk should not be used for human consumption during treatment or for 60 hours (5 milkings) after the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Zeromast contains one active ingredient: Cloxacillin Benzathine. This antibiotic has a bacteriostatic effect at low concentrations and is bactericidal at higher concentrations. Its primary activity is against gram-positive organisms, such as *Staphylococcus, Streptococcus* and *Actinomyces pyogenes*. It is not destroyed by staphylococcal penicillinase.

Following infusion Cloxacillin diffuses rapidly through the udder parenchyma and levels in blood plasma increase to a peak between 2 and 8 hours. MIC's for susceptible strains of *Staphylococcus, Streptococcoccus agalactiae, Strep. dysgalactiae, Strep. uberis* and *A. pyogenes* are maintained in milk for more than 32 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Sodium Citrate
Polysorbate 80
Disodium Edetate
Water for Injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of veterinary medicinal product as packaged for sale: 12 months

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

5 ml Low Density Polyethylene (LDPE) disposable syringes, sealed with Low Density Polyethylene (LDPE) syringe plunger.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/033/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 March 1996
Date of last renewal: 21 March 2006

10 DATE OF REVISION OF THE TEXT

May 2019