Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Kefamast Lactating Cow Intramammary suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10ml syringe contains:

Active substances

Cephalexin (Anhydrous)	500 mg
Dihydrostreptomycin (as Dihydrostreptomycin Sulphate).	500 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary Suspension

Smooth pale pink or pale yellow intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating cow.

4.2 Indications for use, specifying the target species

For the treatment of mastitis caused by organisms susceptible to the combination of cephalexin and dihydrostreptomycin in lactating cows.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

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

Operators should avoid contact with this preparation as occasionally skin allergy may occur.

Penicillins and cephalosporins may cause hypersensitivity 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 that you are sensitized, or if you have been advised not to work with such preparations.

Handle this product with care to avoid exposure.

If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to your doctor. Swelling of the face, lips or eyes, or difficulty 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

The product may be used in pregnant cattle. The product is intended for use in lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The contents of one injector should be infused into each affected quarter, via the teat canal, immediately after milking and at twelve hourly intervals for a total of up to 3 infusions. Before the infusion is made the teat should be thoroughly cleaned and disinfected. Care should be taken to avoid contamination of the injector nozzle after the cap has been removed.

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

Not applicable.

4.11 Withdrawal Period(s)

Milk for human consumption must not be taken from cows during treatment. With cows milked twice daily, milk for human consumption may only be taken from 96 hours (ie. at the eight milking) after the last treatment.

Animals should not be slaughtered for human consumption during treatment. Cows may be slaughtered for human consumption only after 7 days following the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Cefalexin; combinations with other antibacterials.

ATCvet Code: QJ51RD01

5.1 Pharmacodynamic properties

Cefalexin is a broad spectrum penicillinase-resistant beta-lactam antibiotic. It exerts bactericidal action by inhibiting cell wall synthesis. It has a half-life of about 1 hour and is excreted through the kidneys in the urine.

Dihydrostreptomycin is an aminoglycoside antibiotic. The drug binds to the receptors of the 30S subunit of the ribosome where it induces misreading of the genetic code and consequently causes fatal inhibition of ribosomal protein synthesis in the bacteria. The half-life of dihydrostreptomycin is 1-2 hours. It is eliminated entirely by glomerular filtration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan sesquioleate
Hydrogenated soya oil
Arachis oil

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and composition of immediate packaging

A sterile intramammary injection (9g) provided in a 10 ml white, low density, polyethylene intramammary syringe for single use only. Packaged in cartons of 24 syringes.

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

Bimeda Chemicals,
Broomhill Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10126/033/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2008

10 DATE OF REVISION OF THE TEXT

May 2014