1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KEFAMAST Dry Cow Intramammary Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:

Active substances:

Cefalexin	500 mg
Dihydrostreptomycin (as Dihydrostreptomycin Sulphate)	500 mg

Excipients:

Qualitative composition of excipients and other constituents
Cera alba
Liquid paraffin

Smooth, pale pink or pale yellow suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dry cows).

3.2 Indications for use for each target species

For the treatment of sub clinical mastitis infection present at drying off in cows and to assist in preventing new infections occurring during the dry period.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in lactating cows.
Do not use within 40 days of the estimated calving date.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

The feeding of waste milk containing residues of cefalexin to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

This antimicrobial combination should only be used where diagnostic testing has indicated the need for simultaneous administration of each of the active substances.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Operators should avoid contact with this preparation as occasional 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.

People with known hypersensitivity to cefalexin or dihydrostreptomycin should avoid contact with the veterinary medicinal product.

Handle this veterinary medicinal 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 with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:
See section 5.5.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy and lactation

Pregnancy and lactation:
Can be used during pregnancy. This veterinary medicinal product is contraindicated for use in lactating cows.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For intramammary use only.

The contents of one injector should be infused into the teat canal of each quarter immediately after the last milking of the lactation.

Before infusion, the teat should be thoroughly cleaned and disinfected. Care should be taken to avoid contamination of the injector nozzle after the protective cap has been removed.

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: With cows milked twice daily, milk for human consumption may only be taken from 60 hours after calving (that is, from the fifth milking).
If calving occurs within 40 days of treatment, milk for human consumption may only be taken from 40 days plus 60 hours after treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ51RD01

4.2 Pharmacodynamics

Cefalexin is a broad spectrum, penicillinase-resistant beta-lactam antibiotic. It exerts bactericidal action by inhibiting cell wall synthesis.

Dihydrostreptomycin is an aminoglycoside antibiotic. The drug binds to receptors on 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. Aminoglycosides have a synergistic effect with beta-lactam antibiotics.

4.3 Pharmacokinetics

Cefalexin has a half-life of about 1 hour and is excreted through the kidneys in the urine.

The half-life of dihydrostreptomycin is 1-2 hours. It is eliminated entirely by glomerular filtration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 ⁰C.

5.4 Nature and composition of immediate packaging

A sterile intramammary injection provided in 10 ml white low density polyethylene syringes containing 9 g of product for single use only.

Plastic bucket containing 120 syringes.

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

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER

VPA22033/041/001

8. DATE OF FIRST AUTHORISATION

1 October 1988

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

18 August 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).