Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Osmonds Dry Cow Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.5 g syringe contains:

Active substance(s):

Neomycin sulphate	100	mg
Penethamate hydriodide	100	mg
Procaine benzylpenicillin	400	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.
A smooth, off white, oily suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cows.

4.2 Indications for use, specifying the target species

For routine use in cows at drying off, to treat existing intramammary infections and to assist in preventing new infections occurring during the dry period.

4.3 Contraindications

Do not use in lactating cows.

Do not use within 50 days prior to calving.
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 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 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)

Other than the possibility of sensitivity reactions, it is not anticipated that the product will cause any undesirable effects due to the low toxicity of the actives and the method of administration of the product.

4.7 Use during pregnancy, lactation or lay

The product is not recommended for use within 50 days prior to calving. The product is not recommended for use in lactating cows, except at the drying off stage.

4.8 Interaction with other medicinal products and other forms of interactions

There is very little systemic absorption from the udder and the potential for interaction is thus extremely low.

4.9 Amounts to be administered and administration route

The contents of one syringe should be infused into each quarter via the teat canal immediately after the final milking of a lactation.

Before infusion, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion it is advisable to use teat dip or spray.

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

Care should be taken not to overdose.

Overdosing may invalidate the stated milk and meat withdrawal times.

4.11 Withdrawal period(s)

Edible tissues from slaughtered animal: 28 days.

Milk: 96 hours post calving in cows with a dry period of more than 50 days.
50 days plus 96 hours for cows with a period of 50 days or less.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use, Beta-lactam antibacterials with other antibacterials
ATCvet Code: QJ51RC

5.1 Pharmacodynamic properties

Osmonds Dry Cow is an intramammary product intended for administration to cows at drying off, to treat existing intramammary infections and to assist in preventing new infections occurring during the dry period.

The product contains an aminoglycoside (neomycin sulphate) and two penicillin derivatives (procaine benzyl penicillin and penethamate hydriodide).

Aminoglycosides disturb the permeability of the bacterial cell membrane by an effect exerted during cell wall development. Once the aminoglycoside has entered the cell, it binds to receptors on the ribosome, inducing misreading of the genetic code. Neomycin in common with other aminoglycosides has activity predominantly against gram negative organisms.

Penicillins act by interfering with microbial cell wall synthesis. They inhibit the activity of transpeptidase enzymes which catalyse cross linkage of the glycopeptide polymer units that form the cell wall.

Procaine benzylpenicillin is a complex, sparingly soluble organic salt of benzyl penicillin and its use is intended to delay release of the active penicillin moiety at the site of administration and so give rise to a longer duration of action than would be expected from benzyl penicillin.

Penethamate hydriodide is an ester of benzyl penicillin which is hydrolysed at pH 7.3 with the liberation of free penicillin. It therefore has the mode of action and spectrum of activity of benzyl penicillin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Aluminium stearate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Syringes are for single-use only.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Low Density Polyethylene (LDPE) intramammary syringe, containing 4.5g intramammary suspension.
Syringes packed in cartons of 24 syringes or buckets of 120 syringes.

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
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Airton Road
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 October 1987
Date of last renewal: 30 September 2007

10 DATE OF REVISION OF THE TEXT

May 2019