Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Teat Seal Non Antibiotic 2.6 g Intramammary suspension, Dry Cow

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Bismuth subnitrate 2.6g per 4g syringe

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.
Greyish white, smooth oily suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Dairy cows at the end of lactation.

4.2 Indications for use, specifying the target species

The veterinary medicinal product is indicated for the prevention of new intramammary infections throughout the dry period. This results in a reduction in the incidence of subclinical mastitis in cows at calving, and of clinical mastitis in the dry period and the subsequent lactation (for at least 60 days after calving).

4.3 Contraindications

Do not use in the lactating cow.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Not intended for use in cows with suspected or confirmed mastitis at drying off. If a sealed quarter develops clinical mastitis the affected quarter should be stripped out manually before appropriate antibacterial therapy is instituted.

It is recommended that the veterinary medicinal product be used as part of a herd approach to dry cow management and mastitis control. Cows considered likely to be free of subclinical mastitis should be given the veterinary medicinal product at drying off according to the criteria below. Other animals should be managed in accordance with an approved mastitis control plan or specific veterinary advice.

For practical purposes, selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of subclinical mastitis or bacteriological sampling. It is particularly important that, prior to treatment, an individual cell count be obtained from any cow with a history of clinical mastitis during the previous lactation. As a guide, cows with average cell counts less than 200,000 cells/ml before drying off may be

given the veterinary medicinal product . A minor increase (cell count up to 250,000 cells/ml) during the last 4 weeks before drying off is normal and may be ignored. In case of doubt, veterinary advice should be sought.

For single use only.

Special safety precautions to be taken by the person administering the veterinary medicinal product to animals
None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The veterinary medicinal product should not be administered during lactation. If accidentally used in a lactating cow the seal should be stripped out manually and no additional precautions are needed.

The veterinary medicinal product is safe for use in pregnant animals. At calving, the seal may be stripped out of the teat by hand or may be ingested by the calf. Ingestion of the veterinary medicinal product by the calf is safe and produces no adverse effects.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For intramammary infusion.
Infuse the contents of one syringe of the veterinary medicinal product into each udder quarter immediately after the last milking of the lactation (at drying off.). Do not massage the teat or udder after infusion of the product.

As the veterinary medicinal product possesses no antimicrobial activity, it is essential that the teat is thoroughly cleaned, and that it is allowed to dry prior to infusion. Infuse aseptically and take care to avoid contamination of the syringe nozzle. Following infusion it is advisable to use an appropriate teat dip or spray.

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

Twice the recommended dose has been administered to cows with no adverse effects.

4.11 Withdrawal Period(s)

Meat and offal: zero days
Milk: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Various products for teats and udder.
ACT Vet Code: QG52X

5.1 Pharmacodynamic properties

Infusion of the veterinary medicinal product into each udder quarter produces a seal in the teat that provides an immediate and long lasting physical barrier to entry of bacteria and other mastitis causing organisms. By preventing new intramammary infections during the dry period the veterinary medicinal product thereby also reduces the incidence of clinical mastitis in the next lactation.

5.2 Pharmacokinetic properties

Bismuth subnitrate is not absorbed from the mammary gland, but resides as a seal in the teat until physically removed. (Shown in cows with a dry period up to 100 days).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Aluminium di tri-stearate
Colloidal anhydrous silica

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Primary packaging: Low-density polyethylene syringe with a smooth, tapered hermetically sealed nozzle.
Marketing presentations: boxes of 24, 60 and 120 syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Cross Vetpharm Group Ltd.
Broomhill Road
Tallaght
Dublin 24
IRELAND
trading as Osmonds

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10960/045/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th April 2009

10 DATE OF REVISION OF THE TEXT