SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mastiseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (IE, UK)
Boviseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (DE, PL, IT, NL, ES, AT, BE, CZ, EE, EL, HU, LT, LV, PT, SK)
Boviseal Intramammary Suspension for Cattle (Dry Cow) (FR)
Boviseal vet 2.6 g Intramammary Suspension for Cattle, Dry Cow (FI)
Boviseal (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g intramammary syringe contains:
Active substance:
Bismuth subnitrate, heavy 2.6 g

For the 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

Cattle (dairy cattle 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).
It is recommended that the veterinary medicinal product be used as part of a herd approach to dry cow management and mastitis control.

4.3 Contraindications

Do not use in the lactating cow.
Do not use in cases of known hypersensitivity to the active substance or any of the excipients.
Do not use in cows with suspected or confirmed mastitis at drying off. See section 4.5.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

It is good practice to observe dry cows regularly for signs of clinical mastitis.
If a sealed quarter develops clinical mastitis the affected quarter should be stripped out manually before appropriate antibacterial therapy is instituted.

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.

In cows that may have sub-clinical mastitis, this product may be used following administration of a suitable dry cow antibiotic treatment to the infected quarter.

To reduce the risk of contamination, do not immerse the syringe in water.

For single use only.

Special safety precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
The veterinary medicinal product can be used during pregnancy. 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.

Lactation:

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.

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 use.

Infuse the contents of one intramammary 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.

Care must be taken not to introduce pathogens into the teat in order to reduce the risk of post-infusion mastitis.

It is essential that the teat is thoroughly cleaned and disinfected, with surgical spirit or alcohol-impregnated wipes as the product possesses no antimicrobial activity.

Allow the teat to dry prior to infusion. Infuse aseptically and take care to avoid contamination of the intramammary 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 periods

Meat and offal: Zero days.
Milk: Zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Various products for teats and udder
ATC 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 particulars

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
Silica colloidal anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

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 intramammary syringe with a smooth, tapered hermetically sealed nozzle.

Marketing presentations: Boxes of 24, 60 and 120 intramammary syringes.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Cross Vetpharm Group Ltd.
Broomhill Road
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 12597/4061

9. DATE OF FIRST AUTHORISATION

19 January 2015

10. DATE OF REVISION OF THE TEXT

January 2015

Approved:  **24/05/2017**