SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK - BOVISEAL 2.6 g intramammary suspension for cattle (dairy cows)
Italy, Spain - EASISEAL 2.6 g intramammary suspension for cattle (dairy cows)
France - MAMISEAL 2.6 g intramammary suspension for cattle (dairy cows)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4g intramammary syringe contains:

Active substance: Bismuth subnitrate, heavy 2.6g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension
Greyish white, smooth, unctuous cream.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (dairy cows).

4.2 Indications for use, specifying the target species

Prevention of new intramammary infections throughout the dry period.

In cows considered likely to be free of sub-clinical mastitis, the product can be used on its own in dry cow management and mastitis control.

Selection of cows for treatment with the product should be based on veterinary clinical judgement. Selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of sub-clinical mastitis or bacteriological sampling.

4.3 Contraindications

See section 4.7. Do not use the product alone in cows with sub-clinical mastitis at drying off. Do not use in cows with clinical mastitis at drying off.
Do not use in the lactating cows.
Do not use in known cases of hypersensitivity to bismuth subnitrate or any of the excipients.

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

Avoid contact with skin or eyes.
Should skin or eye contact occur, wash the affected area thoroughly with water.
If irritation persists, seek medical advice and show this label to the doctor.
If you know that you are allergic to bismuth salts, avoid using this product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
As the product is not absorbed following intramammary infusion, the product can be used in pregnant animals. At calving, the seal may be ingested by the calf. Ingestion of the product by the calf is safe and produces no adverse effects.

Lactation:
The product is contra-indicated for use during lactation. If accidentally used in a lactating cow, a small (up to 2-fold) transient rise in somatic cell count may be observed. In such an event, strip out the seal manually, no additional precautions are necessary.

4.8 Interaction with other medicinal products and other forms of interaction

In clinical trials, the compatibility of the product has only been shown with a cloxacillin-containing dry cow preparation.

4.9 Amounts to be administered and administration route

For intramammary use only.
Infuse the contents of one syringe of the 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. The teats should be wiped until the wipes are no longer visibly dirty. Teats should be 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 clinical adverse effects.

4.11 Withdrawal periods

Meat: Zero days.
Milk: Zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Various products for teats and udder.
ATCvet code: QG52X

5.1 Pharmacodynamic properties

Infusion of the product into each udder quarter produces a physical barrier against the entry of bacteria thereby reducing the incidence of new intramammary infections during the dry period.

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 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 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

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 product 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

Continental Farmaceutica
Rue Laid Burniat, 1
1348 Louvain-la-Neuve
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 41966/4001

9. DATE OF FIRST AUTHORISATION

23 January 2013

10. DATE OF REVISION OF THE TEXT

February 2018