ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbeseal Dry Cow 2.6 g intramammary suspension for cattle [AT, BE, BG, HR, CY, DE, FI, EL, IT, LU, NL, NO, PT, RO, SI, ES, SE, United Kingdom (NI)]
Orbesealer Vet – 2.6 g intramammary suspension for cattle [DK]
Boviseal Dry cow intramammary suspension for cattle [IE]
Orbeseal Dry cow intramammary suspension for cattle [FR]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g intramammary syringe contains:

Active substance:

Bismuth subnitrate, heavy 2.6 g
(equivalent to Bismuth, heavy 1.858 g)

Excipients:

Qualitative composition of excipients and other constituents
Liquid paraffin
Aluminium Di Tri Stearate
Silica, Colloidal Anhydrous

Greyish white, smooth, unctuous intramammary suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dairy cow at drying-off).

3.2 Indications for use for each target species

Prevention of new intramammary infections throughout the dry period.

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

3.3 Contraindications

See section 3.7 “Use during pregnancy, lactation or lay”. Do not use the veterinary medicinal 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 cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Selection of cows for treatment with the veterinary medicinal 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 subclinical mastitis or bacteriology sampling.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 therapy is instituted.
To reduce the risk of contamination, do not immerse the syringe in water.
Use the syringe only once.

Since the veterinary medicinal product does not have antimicrobial activity, in order to minimize the risk of acute mastitis due to poor infusion technique and lack of hygiene (see section 3.6 "Adverse events"), it is crucial to follow the aseptic technique of administration described in section 3.9 "Administration routes and dosage".

Do not administer any other intramammary product following administration of the veterinary medicinal product. In cows that may have sub-clinical mastitis, the veterinary medicinal product may be used following administration of a suitable dry cow antibiotic treatment to the infected quarter.

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

This veterinary medicinal product may cause skin and eye irritation.
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 physician.
People with known hypersensitivity to bismuth salts should avoid contact with the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (dairy cow at drying-off).

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Acute mastitis[1].

[1]Primarily due to poor infusion technique and lack of hygiene. Please refer to sections 3.5 "Special precautions for use" and 3.9 "Administration routes and dosage" regarding the importance of aseptic technique.

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 its local representative or the national competent authority via the national reporting system. See also 'Contact details' section of the package leaflet.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The veterinary medicinal product is not absorbed following intramammary infusion.

Can be used in pregnancy. At calving, the seal may be ingested by the calf. Ingestion of the veterinary medicinal product by the calf is safe and produces no adverse effects.

Lactation:
Do not 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.

3.8 Interaction with other medicinal products and other forms of interaction

In clinical trials, the compatibility of the veterinary medicinal product has only been shown with a cloxacillin-containing dry cow preparation.
See also section 3.5 “Special precautions for safe use in the target species”.

3.9 Administration routes and dosage

Intramammary use only.
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 veterinary medicinal 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.

Under cold conditions the veterinary medicinal product may be warmed to room temperature in a warm environment, to aid syringeability.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

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: Zero days.
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG52X

4.2 Pharmacodynamics

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

4.3 Pharmacokinetics

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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

A 4 g single dose low-density polyethylene intramammary syringe with a smooth, tapered hermetically sealed nozzle.

Available in cardboard boxes of 24, 60 and plastic bucket of 120 syringes.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

To be completed nationally

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25 June 2002.

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

To be completed nationally

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