**ANNEX I**

#### Summary of product characteristics

**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

FATROSEAL 2.6 g intramammary suspension for dry cows (AT, BE, CZ, DE, DK, EE, EL, ES, FR, IE, LU, NL, HU, PL, PT, SK, NI).

1. **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)

**Excipient(s):**

For the full list of excipients, see section 6.1.

1. **PHARMACEUTICAL FORM**

Intramammary suspension.

White to greyish homogeneous suspension.

1. **CLINICAL PARTICULARS**

**4.1. Target species**

Dry 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.

**4.3. Contraindications**

Do not use in lactating cows. 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 cases of hypersensitivity to the active substance or to any of the excipients.

**4.4. Special warnings for each target species**

Selection of cows for treatment with Fatroseal 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.

As a guide, where individual cell counts are available, cows with an average cell count less than 200,000 cells/ml may be given. A minor increase in cell count during the last 4 weeks before drying off is normal and may be ignored.

**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 therapy is instituted.

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

It is important to observe strict aseptic technique for the administration of the product, because it does not have antimicrobial activity. Do not administer any other intramammary product following administration of the product. In cows that may have sub-clinical mastitis, the 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 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.

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:

It can be used in pregnant animals. At calving, Fatroseal 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**

None known.

**4.9. Amounts to be administered and administration route**

For intramammary use only.

Infuse the contents of one intramammary 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.

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

**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 period(s)**

Meat and offal: Zero days.

Milk: Zero hours.

1. **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 there by 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).

1. **PHARMACEUTICAL PARTICULARS**

**6.1. List of excipients**

Aluminium di - tristearate

Silica, colloidal anhydrous

Paraffin, liquid

**6.2. Major incompatibilities**

None known.

**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**

4g low-density polyethylene intramammary syringe with a polyethylene cap.

Pack sizes:

Cardboard box with 24 syringes

Cardboard box with 60 syringes

Cardboard box with 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.

1. **MARKETING AUTHORISATION HOLDER**

FATRO S.p.A. - Via Emilia, 285 - Ozzano dell’Emilia (Bologna), Italy.

1. **MARKETING AUTHORISATION NUMBER**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation:

Date of last renewal:

**10. DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

For animal treatment only.

To be supplied only on veterinary prescription.