SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROSEAL 2.6 g intramammary suspension for dry cows

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)

Excipient(s):

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension.
White to greyish homogeneous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (dairy cows at drying-off).

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 alone 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 known 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 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.

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.
Since the 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 4.6), it is crucial to follow the aseptic technique of administration described in section 4.9.
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
Bismuth salts have been associated with hypersensitivity reactions.
People with known hypersensitivity (allergy) to bismuth salts should avoid contact with the veterinary medicinal product.
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 provided, the cleaning wipes may cause skin and eye irritation in some people due to the presence of isopropyl alcohol and chlorhexidine digluconate. Avoid contact with skin or eyes.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Acute mastitis has been reported very rarely after use of this product, primarily due to poor infusion technique and lack of hygiene. Please refer to sections 4.5 and 4.9 regarding the importance of aseptic technique.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
The product is not absorbed following intramammary infusion, it 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

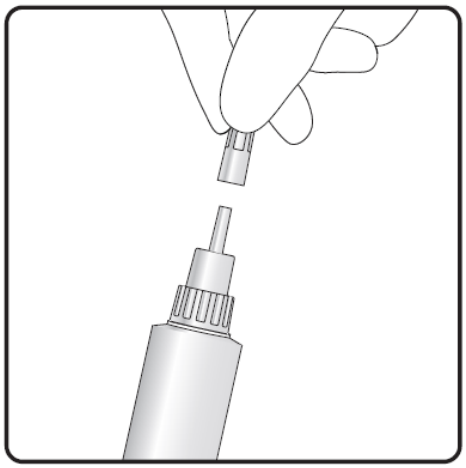
In clinical trials, the compatibility of a comparable teat seal formulation containing bismuth subnitrate has only been shown with a cloxacillin-containing dry cow preparation.
See also section 4.5. “Special precautions for use in animals”.

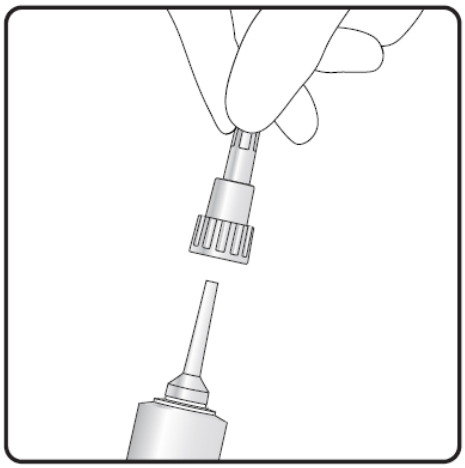
4.9 Amounts to be administered and administration route

For intramammary use only.

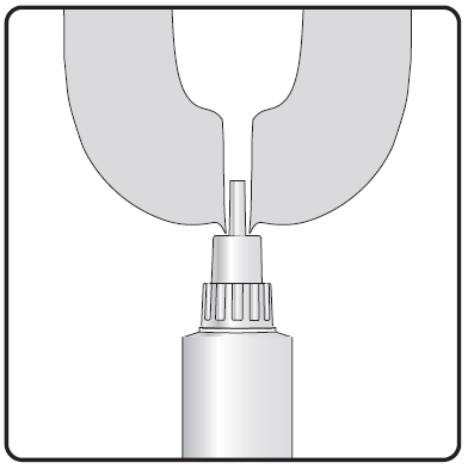
The product has a dual tip nozzle. The cap of the syringe can be partially or fully removed. It is recommended to pinch the teat at the base as it aids in positioning the paste in the teat cistern, sealing the teat canal from the top.
Short tip option: The short tip option allows for a partial insertion technique so that the syringe only needs to be inserted in the teat end.
Long tip option: The long tip option may be used for treatment convenience for example to prevent the tip from flipping out due to a moving or nervous cow.

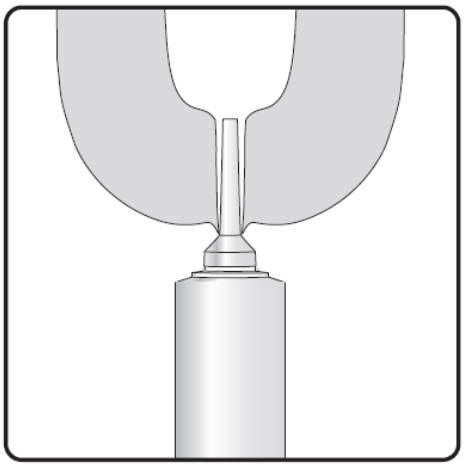
Step 1: Removal of the breakable cap





Step 2: Short or long tip insertion





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 because it is important that the sealant stays in the teat itself and does not enter the udder.

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.

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 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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate
Silica, colloidal anhydrous
Paraffin, liquid

6.2 Major 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

A single dose LDPE intramammary syringe closed with a LDPE cap containing 4 g of suspension.

Package sizes:
Cardboard box with 24 syringes
Cardboard box with 60 syringes
Cardboard box with 120 syringes
Cardboard box with 24 syringes + 24 cleaning wipes
Cardboard box with 60 syringes + 60 cleaning wipes
Cardboard box with 120 syringes + 120 cleaning wipes

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 11557/5002

9. DATE OF FIRST AUTHORISATION

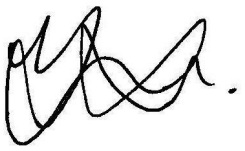
30 March 2022

10. DATE OF REVISION OF THE TEXT

June 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only.
To be completed nationally.



Approved: 09 June 2022