ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROSEAL 2.6 g intramammary suspension for dry cows
Bismuth subnitrate, heavy

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 g intramammary syringe contains:
Active substance: Bismuth subnitrate, heavy 2.6 g (equivalent to Bismuth, heavy 1.858 g).

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

24 x 4 g
60 x 4 g
120 x 4 g

5. TARGET SPECIES

Cattle (dairy cows at drying-off)

6. INDICATION(S)

For OTC products:
The product is indicated for the 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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramammary use only.
Read the package leaflet before use.

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.

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

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.
Do not use the product alone in cows with sub-clinical mastitis at drying off (for more info see “Special warnings” in the package leaflet).
Do not use in cows with clinical mastitis at drying off.
Do not use in lactating cows.
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.

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be completed nationally.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBERS

Vm 11557/5002

17. MANUFACTURER'S BATCH NUMBER

LOT. {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
4 g intramammary syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROSEAL 2.6 g intramammary suspension for dry cows
Bismuth subnitrate, heavy

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Bismuth subnitrate, heavy 2.6 g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use.

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

LOT. {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

FATROSEAL
2.6 g intramammary suspension for dry cows

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
FATRO S.p.A
Via Emilia, 285
Ozzano dell'Emilia (Bologna)
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROSEAL 2.6 g intramammary suspension for dry cows
Bismuth subnitrate, heavy

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each 4 g intramammary syringe contains:

Active substance:

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

White to greyish, homogeneous suspension.

4. INDICATIONS

The product is indicated for the 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.

5. CONTRAINDICATIONS

Do not use the product alone in cows with sub-clinical mastitis at drying off (see section "Special warnings").
Do not use in cows with clinical mastitis at drying off.
Do not use in lactating cows. 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 the product can be easily manually stripped out and no additional precautions are necessary.

Do not administer any other intramammary product following administration of the product.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

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 12 and 8 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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (dairy cows at drying-off).

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

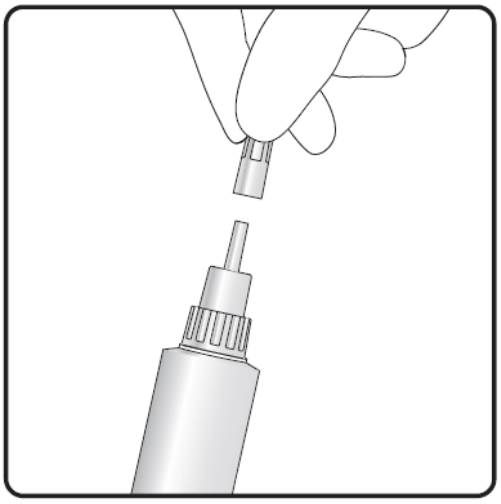
For intramammary use only.
Infuse the contents of one intramammary syringe of the product into each udder quarter immediately after the last milking of the lactation at drying off.
Do not massage the teat or udder after infusion of the product because it is important that the sealant stays in the teat itself and does not enter the udder.

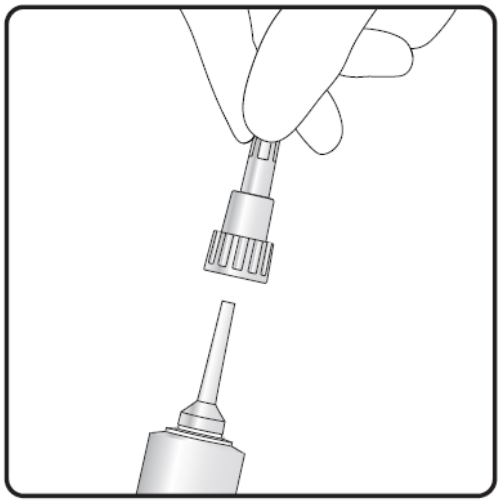
Care must be taken not to introduce pathogens into the teat. It is essential that strict aseptic techniques are used for the infusion of the product as it possesses no antimicrobial activity. Failure to follow these recommendations can lead to serious cases of post-infusion mastitis and even death of the animal.

1. All teats need to be thoroughly cleansed and disinfected prior to infusion of the product. Ensure sufficient time is allocated to treat each animal and do not combine this with other husbandry activities.
2. Ensure animals are appropriately restrained in hygienic conditions. Keep syringes clean and DO NOT immerse in water.
3. A separate pair of clean disposable gloves should be worn for the treatment of each cow.

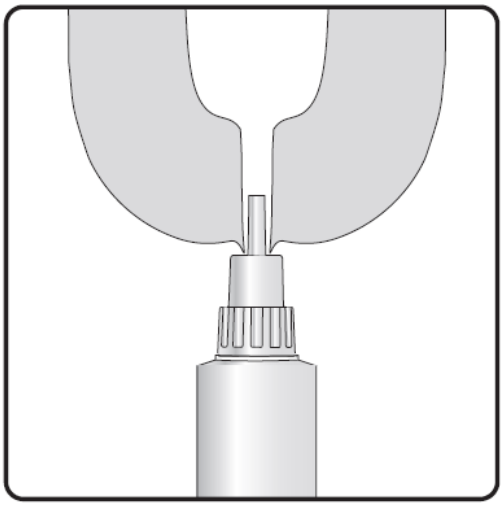
4. Start with a visibly clean, dry teat and udder. If teats are obviously dirty then clean off dirt from teats only, with moistened disposable paper towels and dry thoroughly. Dip teats in a rapid-acting pre-dip, leave for 30 seconds, then wipe each teat completely dry with separate disposable paper towels. Strip fore milk into a strip cup and discard.
5. Thoroughly disinfect the whole surface of the teat with a disposable spirit/alcohol soaked swab. Studies indicate that the most effective means of teat cleaning involves the use of swabs freshly prepared from clean dry cotton wool soaked in surgical spirit (or the equivalent). If this is not available, then the supplied sterile swabs can be used. Clean the teats furthest away from you first, to avoid contaminating clean teats.
6. Gently scrub each teat end with new individual, disposable, spirit/alcohol swabs, until both teat end and swab are visibly clean.
7. Remove the cap from the intramammary tube, being careful not to touch the nozzle.
   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.

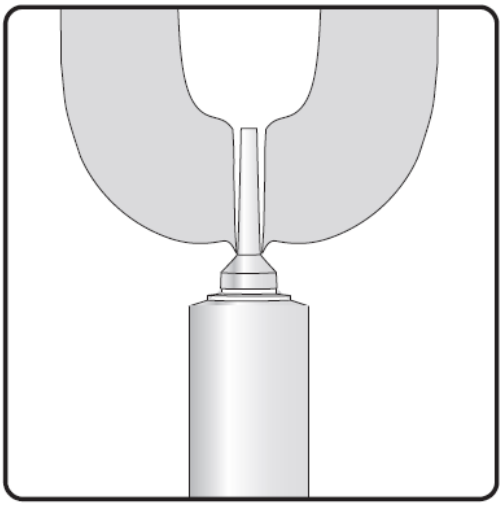
Step 1: Removal of the breakable cap





Step 2: Short or long tip insertion





8. Grip the teat base firmly between your fingers at the junction with the udder. Turn the teat to a slight angle. Infuse the contents of the syringe into the bottom portion of the teat below where you are pinching the teat avoiding contaminating the teat end. Infuse teats in the opposite order to cleaning i.e. treat the quarters closest to you first. Do not massage the product into the udder.
9. Apply a post-milking teat disinfectant and confine the treated cows to a yard where they should stand for at least 30 minutes to allow the teat canal to close.

9. ADVICE ON CORRECT ADMINISTRATION

It is important that you read the instructions before using this product.
Great care should be taken in maintaining cleanliness when administering the product in order to reduce the risk of potentially fatal post-infusion mastitis.
Full advice on teat cleaning technique prior to tubing is included in the instructions and should be followed.
Under cold conditions the product may be warmed to room temperature in a warm environment, to aid syringeability.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Zero days.

Milk: Zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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.

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 “Adverse reactions”), it is crucial to follow the aseptic technique of administration described in “Method of administration”.
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.

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.

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 “Special warnings for each target species”.

Overdose (symptoms, emergency procedures, antidotes):
Twice the recommended dose has been administered to cows with no clinical adverse effects.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

15. OTHER INFORMATION

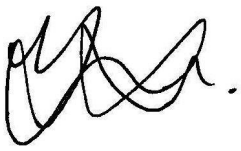
Most of the seal comes out at the first stripping or suckling after calving, but small amounts may occasionally be seen for a few days as flecks on the filter. The product can be differentiated from mastitis by its texture.
The milking machine should not be used to remove the product from the teat.
After calving, the following steps are recommended for the effective removal of the product to minimise residual product entering the milking machine.
1. Pinch the teat at the top and strip quarter 10-12 times prior to first milking.
2. Strip foremilk and check for residual product for first few milkings.
3. Inspect mastitis filters and milk sock for evidence of residual product after every milking.

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.

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.



Approved: 09 June 2022