PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box:
24 syringes
60 syringes
120 syringes
24 syringes + 24 cleaning wipes
60 syringes + 60 cleaning wipes
120 syringes + 120 cleaning wipes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fatroseal 2.6 g intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

24 syringes
60 syringes
120 syringes
24 syringes and 24 cleaning wipes
60 syringes and 60 cleaning wipes
120 syringes and 120 cleaning wipes

4. TARGET SPECIES

Cattle (dairy cows at drying-off).

5. INDICATIONS

For OTC products:

The veterinary medicinal 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 veterinary medicinal product can be used alone in dry cow management and mastitis control.

6. ROUTES OF ADMINISTRATION

Intramammary use.

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

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: Fatro S.p.A.

Distributed in GB&NI by: DUGV (UK) Ltd., Union House, 111 New Union Street, Coventry, CV1 2NT, UK
uksales@dugganvet.com

14. MARKETING AUTHORISATION NUMBER

Vm 11557/5002

15. 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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 4 g intramammary syringe contains:
Bismuth, heavy 1.858 g equivalent to Bismuth subnitrate, heavy 2.6 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fatroseal 2.6 g intramammary suspension for dry cows

2. Composition

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

White to greyish, homogeneous suspension.

3. Target species

Cattle (dairy cows at drying-off).

4. Indications for use

The veterinary medicinal 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 veterinary medicinal product can be used alone in dry cow management and mastitis control.

5. Contraindications

Do not use the veterinary medicinal 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 veterinary medicinal product can be easily manually stripped out and no additional precautions are necessary.
Do not administer any other intramammary product following administration of the veterinary medicinal product.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
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 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 "Adverse events"), it is crucial to follow the aseptic technique of administration described in "Dosage for each species, routes and method of administration".
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:
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 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.

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 veterinary medicinal product is not absorbed following intramammary infusion. Can be used during 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:
The veterinary medicinal 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 precaution for safe use in the target species".

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

Special restrictions for use and special conditions for use:

Major incompatibilities:
Not applicable.

7. 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 "Special warnings" and "Dosage for each species, routes and method of administration" regarding the importance of aseptic technique.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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

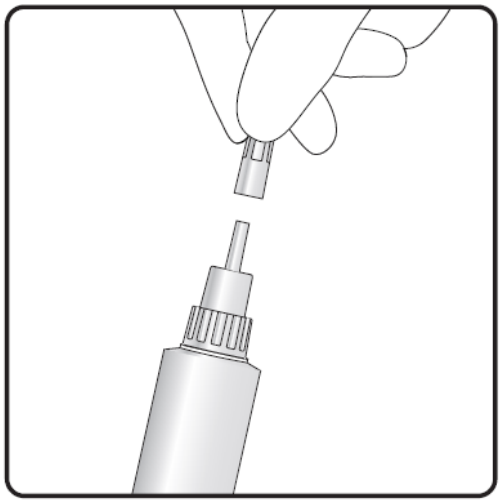
Care must be taken not to introduce pathogens into the teat. It is essential that strict aseptic techniques are used for the infusion of the veterinary medicinal product as it possesses no antimicrobial activity. Failure to follow these recommendations can lead to serious cases of post-infusion mastitis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

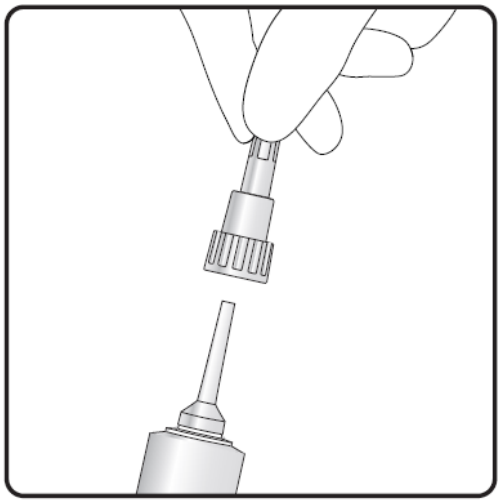
1. All teats need to be thoroughly cleansed and disinfected prior to infusion of the veterinary medicinal product. Ensure sufficient time is allocated to treat each animal and do not combine this with other husbandry activities.
2. Ensure animals are appropriately restrained in hygienic conditions. Keep 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 veterinary medicinal 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.

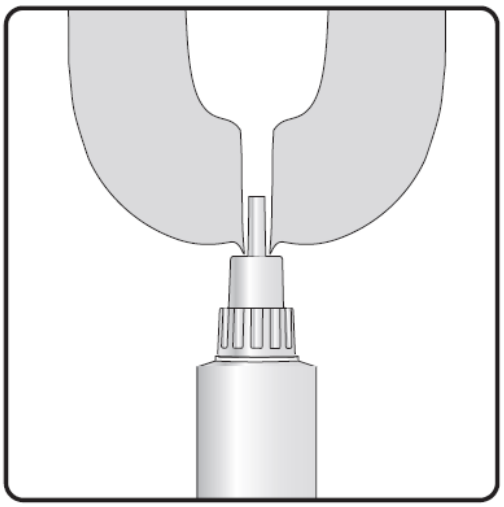
- Short tip option: The short tip option allows for a partial insertion technique so that the syringe only needs to be inserted in the teat end.
- Long tip option: The long tip option may be used for treatment convenience for example to prevent the tip from flipping out due to a moving or nervous cow.

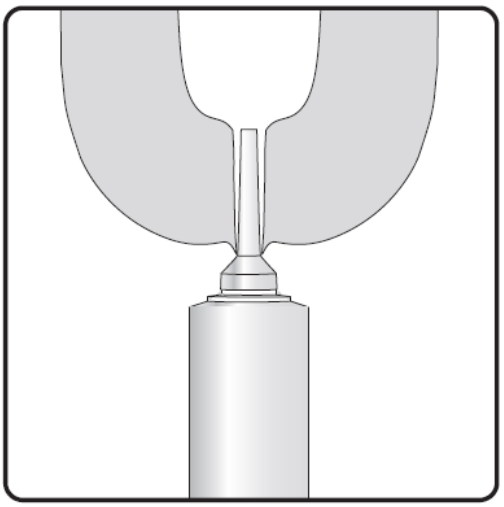
Step 1: Removal of the breakable cap





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 veterinary medicinal 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 veterinary medicinal product.
Great care should be taken in maintaining cleanliness when administering the veterinary medicinal 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 veterinary medicinal product may be warmed to room temperature in a warm environment, to aid syringeability.

10. Withdrawal periods

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 after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 11557/5002

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Fatro S.p.A.
Via Emilia, 285
40064, Ozzano dell'Emilia
Italy

Local representatives and contact details to report suspected adverse reactions:

DUGV (UK) Ltd.
Union House
111 New Union Street
Coventry, CV1 2NT, UK
Phone: +353 (0) 504 43169

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

17. 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 veterinary medicinal product can be differentiated from mastitis by its texture.
The milking machine should not be used to remove the veterinary medicinal product from the teat.
After calving, the following steps are recommended for the effective removal of the veterinary medicinal product to minimise residual veterinary medicinal 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 veterinary medicinal product for first few milkings.
3. Inspect mastitis filters and milk sock for evidence of residual veterinary medicinal product after every milking.

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.

POM-V

Gavin Hall
Approved: 04 July 2025