PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box or Polyethylene bucket }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubroseal blue Dry Cow 2.6 g intramammary suspension for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

20 x 4g
60 x 4g
120 x 4g

4. TARGET SPECIES

Cattle (dairy cows at drying off).

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

For intramammary use only.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Protect from light.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

{Univet company logo}

Local representative:
Boehringer Ingelheim Animal Health UK Ltd.

{Boehringer Ingelheim company logo}

14. MARKETING AUTHORISATION NUMBERS

Vm 05150/5000

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS { Low-density polyethylene pre-filled syringe with a smooth, tapered hermetically sealed nozzle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubroseal Blue Dry Cow 2.6 g Intramammary Suspension for Cattle

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Bismuth subnitrate, heavy 2.6 g/4 g.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubroseal Blue Dry Cow 2.6 g Intramammary Suspension for Cattle

2. COMPOSITION

Each 4 g intramammary syringe contains:

Active substance:
Bismuth subnitrate, heavy 2.6 g

Excipient:
Indigo Carmine AL Lake E 132 0.02 g

A blue intramammary 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 subclinical mastitis the veterinary medicinal product can be used on its own in dry cow management and mastitis control. 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 sub-clinical mastitis or bacteriology sampling.

5. CONTRAINDICATIONS

Do not use in lactating cows.
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.

6. SPECIAL WARNINGS

None.

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. It is important to observe strict aseptic technique for the administration of the veterinary medicinal product because the veterinary medicinal product does not have antimicrobial activity. Do not administer any other intramammary veterinary medicinal product following administration of this 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:

Wash hands after use.

The disinfecting towels provided with the intramammary veterinary medicinal product contain isopropyl alcohol. Wear protective gloves if skin irritation due to isopropyl alcohol is known or suspected. Avoid contact with eyes because isopropyl alcohol can cause eye irritation.

Pregnancy and lactation:

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.

This 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.

Overdose:

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

Major incompatibilities:

Not applicable.

7. ADVERSE EVENTS

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 Advice on correct administration regarding the importance of aseptic technique.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 local representatives using the contact details at the end of this leaflet, or via your national reporting system.

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

For intramammary use only.

Infuse the contents of one 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 disinfecting towels. The teats should be wiped until the disinfecting towels 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.

Refer below to advice on correct administration.

9. ADVICE ON CORRECT ADMINISTRATION

Advice to herdsmen:

It is important that you read the instructions before using this veterinary medicinal product. Great care should be taken in maintaining cleanliness when administering this 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.

Administration:
Care must be taken not to introduce pathogens into the teat. It is essential that strict aseptic techniques are used for the infusion of this 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.

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. Infuse the contents of the syringe into 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.

8. 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.

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.
Do not store above 25°C.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and syringe label after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

FOR GB/NI ONLY: Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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 NUMBERS AND PACK SIZES

A 4g polyethylene intramammary syringe consisting of a barrel with plunger and a polyethylene dual-cap.

Cardboard box of 20 syringes and 20 disinfecting towels.
Polyethylene bucket of 60 syringes and 60 disinfecting towels.
Polyethylene bucket of 120 syringes and 120 disinfecting towels.

Not all pack sizes may be marketed.

Vm 05150/5000

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:
Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

Local representatives and contact details to report suspected adverse reactions:

Boehringer Ingelheim Animal Health UK Ltd.

17. OTHER INFORMATION

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

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 and colour.

Twice the recommended dose has been administered to cows with no clinical adverse effects. Under cold conditions the veterinary medicinal product may be warmed to room temperature in a warm environment to aid syringeability.

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. The milking machine should not be used to remove the veterinary medicinal product from the teat.

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.

Gavin Hall

Approved: 19 December 2024