ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

Bismuth subnitrate, heavy

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

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

5. TARGET SPECIES

Cattle (dairy cows at drying off)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For intramammary use only.

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: Zero days.
Milk: Zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not use any other intramammary product following the administration of the

product.
For single use only.
Wash hands after use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light

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

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

For animal treatment only

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

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05150/4006

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

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

Bismuth subnitrate, heavy 2.6g

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

4. ROUTE(S) OF ADMINISTRATION

For intramammary use only.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
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:
Ubroseal blue Dry Cow 2.6 g intramammary suspension for cattle

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:

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubroseal blue Dry Cow 2.6 g intramammary suspension for cattle
Bismuth subnitrate, heavy

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

The product is a blue suspension.
Each 4 g intramammary syringe contains 2.6 g Bismuth subnitrate, heavy.

Excipient
Indigo Carmine AL Lake E 132

4. INDICATION(S)

The 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 product can be used on its own in dry cow management and mastitis control. Selection of cows for treatment with the 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 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 the lactating cow. If lactating cows are accidentally infused, a small (up to 2-fold) transient rise in somatic cell count may be observed, but the seal can easily be stripped out manually and no additional precautions are necessary.
Do not administer any other intramammary product following the 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

None known. 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.

7. TARGET SPECIES

Cattle (dairy cows at drying off)

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

For intramammary use only.

Dosage: One syringe into each udder quarter immediately after the last milking of the lactation (at drying off). Do not massage the teat or udder after infusion.

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 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 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

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 WARNING(S)

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 the product does not have antimicrobial activity. Do not administer any other intramammary product following administration of this 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:
Wash hands after use.
The cleaning towels provided with the intramammary 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 product by the calf is safe and produces no adverse effects.
This 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 (symptoms, emergency procedures, antidotes):
Twice the recommended dose has been administered to cows with no clinical adverse effects.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2020

15. OTHER INFORMATION

Infusion of the 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 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 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 product to minimise residual product entering the milking machine. The milking machine should not be used to remove the 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 product for first few milkings.
3. Inspect mastitis filters and milk sock for evidence of residual product after every milking.
Boxes of 20, 60 and 120 syringes. Not all pack sizes may be marketed.

Approved 20 July 2022