SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ubroseal blue Dry Cow 2.6 g intramammary suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4g intramammary syringe contains:

Active substance:
Bismuth subnitrate, heavy 2.6g

Excipients:
Indigo Carmine AL Lake E 132 0.02g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension
Blue 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 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 bacteriological sampling.

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

None.

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. 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.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during pregnancy, lactation or lay

Pregnancy:
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.

Lactation:
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.

4.8 Interaction with other medicinal products and other forms of interaction

None Known

4.9 Amounts to be administered and administration route

For intramammary use only.
Infuse the contents of one 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.

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 thereby 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

Paraffin, liquid
Aluminium Di Tri Stearate
Silica, colloidal anhydrous
Indigo Carmine AL Lake E 132

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light

6.5 Nature and composition of immediate packaging

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

Cardboard box of 20 syringes and 20 cleaning towels
Polyethylene bucket of 60 syringes and 60 cleaning towels
Polyethylene bucket of 120 syringes and 120 cleaning towels

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

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 05150/4006

9. DATE OF FIRST AUTHORISATION

08 February 2018

10. DATE OF REVISION OF THE TEXT

July 2022

Approved 20 July 2022