ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX/PLASTIC BUCKET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DrySeal 2.6 g intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 g syringe contains 2.6 g bismuth subnitrate

3. PACKAGE SIZE

20 syringes
144 syringes

4. TARGET SPECIES

Cattle (dairy cows at drying off)

5. INDICATIONS

For veterinary medicinal products not subject to veterinary prescription

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 on its own in dry cow management and mastitis control.

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once the applicator syringe is opened use immediately.

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

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DrySeal [AT, CZ, DE, HU, IE, IT, PL, SK, UK(NI)]

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2.6 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

DrySeal 2.6 g intramammary suspension for cattle

2. Composition

Each 4 g syringe contains 2.6 g bismuth subnitrate, heavy (equivalent to 1.858 g bismuth, heavy)

White to off-white intramammary suspension.

3. Target species

Cattle (dairy cows at drying off)

4. Indications for use

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 on its own in dry cow management and mastitis control.

5. Contraindications

Do not use in lactating cows.
Do not use the veterinary medicinal product alone in cows with sub-clinical mastitis.
Do not use in cows with clinical mastitis.
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 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 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, it is crucial to minimize the risk of acute mastitis due to poor infusion technique and lack of hygiene (see 'Adverse events' section), follow the aseptic technique of administration described in 'Advice on correct administration' section.
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.
Do not administer any other intramammary product following administration of the veterinary medicinal product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 the package leaflet or label to the physician.
Bismuth salts have been associated with hypersensitivity reactions. If you know that you are allergic to bismuth salts, avoid using this veterinary medicinal product. If you develop symptoms following exposure, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

Disinfectant wipes:
The disinfectant wipes may cause skin and eye irritation due to the presence of isopropyl alcohol. Avoid eye contact. Avoid prolonged contact with skin. Avoid inhalation of the vapour. The wearing of gloves may prevent skin irritation.
Wash hands after use.

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

7. Adverse events

Cattle (dairy cows 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 "Special warnings" and "Advice on correct administration" sections 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

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).

9. Advice on correct administration

Intramammary use.

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 to reduce the risk of post infusion
mastitis.

It is essential that the teat is thoroughly cleaned and disinfected before infusion, with the alcohol-impregnated wipes provided or equivalent. 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.

The veterinary medicinal product has a dual tip nozzle (see Figure 1). The cap of the syringe can be partially or fully removed providing two nozzle options. It is recommended to pinch the teat at the teat base as it aids in positioning the paste in the teat cistern, sealing the teat canal from the top.

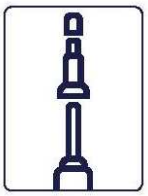
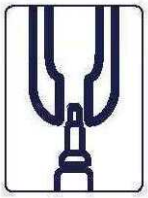
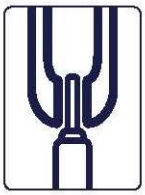


Figure 1

Option 1: The short nozzle option allows for a partial insertion to minimize intrusion into the teat.
Option 2: The long nozzle option may be used for treatment convenience for example to help keep the tip inserted during administration to a moving or nervous cow.



Option 1: For short nozzle intramammary administration hold the barrel of the intramammary syringe and the base of the cap in one hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the intramammary syringe) Take care not to contaminate the nozzle.



Option 2: For full nozzle intramammary administration remove the cap fully by holding the barrel of the intramammary syringe firmly on one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.

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

Once the applicator syringe is opened use immediately.

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. (AT, CZ, DE, HU, IT, PL, SK, UK(NI))
Veterinary medicinal product not subject to prescription. (IE)

14. Marketing authorisation numbers and pack sizes

Vm 52127/3000

Carton box of 20 syringes and alcohol disinfectant wipes.
Plastic bucket of 144 syringes and alcohol disinfectant 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 contact details to report suspected adverse reactions:
Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

Manufacturer responsible for batch release:
Univet Limited, Tullyvin, Cootehill, Co. Cavan., Ireland

Gavin Hall

Approved: 09 August 2024