1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DrySeal intramammary suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g syringe contains:

Active substance:
2.6 g bismuth subnitrate, heavy
(equivalent to 1.858 g bismuth, heavy)

Excipients:

Qualitative composition of excipients
Paraffin, liquid
Aluminium Di Tri Stearate
Silica, Colloidal Anhydrous

White to off-white intramammary suspension

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dairy cows at drying off)

3.2 Indications for use for each target species

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.

3.3 Contraindications

See section 3.7.
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.

3.4 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.

3.5 Special precautions for use

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 section 3.6), follow the aseptic technique of administration described in section 3.9.
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 sections 3.5 and 3.9 regarding the importance of aseptic technique.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder, or its local representative, or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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:
Do not 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.

3.8 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 section 3.5.

3.9 Administration routes and dosage

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 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. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

ATCvet code: QG52X

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Bismuth subnitrate is not absorbed from the mammary gland, but resides as a seal in the teat until physically removed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

A 4 g single dose low-density polyethylene intramammary syringe with a smooth, tapered hermetically sealed nozzle with a low-density polyethylene cap and plunger.
Pack sizes:
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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/069/001

8. DATE OF FIRST AUTHORISATION

10/07/2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).