1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TruSeal 2.6 g intramammary suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g intramammary syringe contains:

Active substance:
Bismuth subnitrate, heavy 2.6 g

Excipients:

Qualitative composition of excipients and other constituents
Paraffin, liquid
Aluminium di tri stearate
Silica, colloidal anhydrous

A 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.

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 bacteriological sampling.

3.3 Contraindications

Do not use in lactating cows. See section 3.7. 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.

3.4 Special warnings

None.

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. 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (dairy cow at dry-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:
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.

Lactation:
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.

3.8 Interaction with other products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

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:

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 (shown in cows with a dry period up to 100 days).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.

Protect from light.

5.4 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 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.

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 applicable national collection systems.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/056/001

8. DATE OF FIRST AUTHORISATION

06/09/2024

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

25/10/2024

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