SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTIC SEAL 2.6 g intramammary suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intramammary syringe (4 g) contains:
Active substance:
Bismuth subnitrate, heavy 2.6 g (equivalent to bismuth heavy 1.858 g)

Excipients:

Qualitative composition of excipients and other constituents
Aluminium stearate
Silica, colloidal anhydrous
Liquid paraffin

White suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dairy cows at drying-off).

3.2 Indications for use for each target species

For the prevention of new intramammary infections throughout the dry period.
In cows considered likely to be free of subclinical mastitis, the veterinary medicinal product can be used on its own in dry cow management and mastitis control.

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 substances or to any of the excipients.

3.4 Special warnings

The use of the veterinary medicinal product is recommended as a part of herd health management to prevent new intramammary infections. 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 somatic cells count history in 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 advisable to observe dry cows regularly for possible signs of clinical mastitis. If a sealed quarter develops clinical mastitis, the affected quarter should be stripped out manually before appropriate antibiotic therapy is instituted.
To avoid contamination, do not immerse the intramammary syringe in water. Use the intramammary syringe only once.

Since the veterinary medicinal product does not have antimicrobial activity, in order to minimize the risk of acute mastitis due to poor infusion technique and lack of hygiene (see section 3.6), it is crucial to follow the aseptic technique of administration described in section 3.9.
Do not administer any other intramammary product following administration of the 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:

People with known hypersensitivity to bismuth salts or paraffin should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may cause skin and eye irritation. Avoid contact with skin or eyes.
Personal protective equipment consisting of rubber gloves should be worn when handling the veterinary medicinal product.
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 the label to the physician.
Cleaning wipes: contain isopropyl alcohol and may therefore cause skin and eye irritation. Avoid contact with eyes. Avoid prolonged contact with skin.
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*

* these symptoms are mainly caused by poor infusion technique and poor hygiene. The importance of aseptic technique is described in sections 3.5 and 3.9.

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.
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:
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 the veterinary medicinal product has only been demonstrated with a cloxacillin-containing dry cow veterinary medicinal product. See also section 3.5 “Special precautions for safe use in the target species”.

3.9 Administration routes and dosage

Intramammary use.
Infuse the content 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 product because it is important that the sealant stays in the teat itself and does not enter the udder. It is recommended to compress the teat at its base during application.

Care must be taken not to introduce pathogens into the teat in order to reduce the risk of post-infusion mastitis.
As the veterinary medicinal product does not have antimicrobial activity, it is essential that the teat is thoroughly cleaned and disinfected before infusion with the alcohol-impregnated wipes provided or other suitable technique. The teats should be wiped until there is no visible dirt collected on the wipe. The teats should be allowed to dry prior to infusion. Infuse aseptically and take care to avoid contamination of the intramammary 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 without the risk of its contamination, to aid syringeability.

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

Twice the recommended dose has been administered to cows without any 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 seal in the teat that provides an immediate and long-lasting physical barrier against the entry of bacteria causing mammary gland diseases. By preventing new intramammary infections during the dry period the veterinary medicinal product thereby also reduces the incidence of clinical mastitis in the next lactation.

4.3 Pharmacokinetics

Bismuth subnitrate is not absorbed from the mammary gland, but resides as a seal in the teat until removed manually (shown in cows with a dry period up to 100 days).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Do not refrigerate or freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

A single dose LDPE intramammary syringe (LDPE cover, LDPE cuff, LDPE plunger) closed with a LDPE cap containing 4 g of suspension and packed in a cardboard box or in a plastic container with a lid. Each package includes disinfectant wipes moistened with 65% v/v isopropyl alcohol solution (2.4 ml/wipe) to clean teats.

Package sizes:
Cardboard box with 24 syringes + 24 cleaning wipes.
Plastic container with 160 syringes + 160 cleaning 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

Bioveta a.s.

7. MARKETING AUTHORISATION NUMBER

Vm 46608/3003

8. DATE OF FIRST AUTHORISATION

25 July 2024

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

July 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 25 July 2024