LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Paper box with 24 intramammary syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTIC SEAL 2.6 g intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

24 x 4 g
Each package includes 24 cleaning wipes.

4. TARGET SPECIES

Cattle (dairy cows at drying-off).

5. INDICATIONS

For products not subject to veterinary prescription
To be completed nationally.

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Protect from light.

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

Bioveta, a.s.

14. MARKETING AUTHORISATION NUMBERS

Vm 46608/3003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic container with a lid with 160 intramammary syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTIC SEAL 2.6 g intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

160 x 4 g
Each package includes 160 cleaning wipes.

4. TARGET SPECIES

Cattle (dairy cows at drying-off).

5. INDICATIONS

For products not subject to veterinary prescription
To be completed nationally.

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Protect from light.

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

Bioveta, a.s.

14. MARKETING AUTHORISATION NUMBERS

Vm 46608/3003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label – intramammary syringe 4 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MASTIC SEAL

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

MASTIC SEAL 2.6 g intramammary suspension for cattle

2. Composition

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

White suspension

3. Target species

Cattle (dairy cows at drying-off).

4. Indications for use

For the prevention of new intramammary infections throughout the dry period.
In cows considered likely to be free of subclinical mastitis, is not expected, 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 (see section 6).
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 case of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

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.

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 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 7), it is crucial to follow the aseptic technique of administration described in section 9.
Do not administer any other intramammary product following administration of the product.
In cows that may have subclinical 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.

Pregnancy:
The veterinary medicinal product is not absorbed following intramammary infusion. Can be used in 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.

Interaction with other medicinal products and other forms of interaction:
In the 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 6 “Special precautions for safe use in the target species”.

Overdose:
Twice the recommended dose has been administered to cows without any adverse effects.

Major incompatibilities:
None known.

7. 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 6 and 9.

Reporting adverse events is important. It allows continuous safety monitoring of a 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: <{national details}>

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

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 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.

9. Advice on correct administration

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.

10. Withdrawal periods

Meat and offal: Zero days.

Milk: Zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not refrigerate or freeze.
Protect from light.
Shelf life after first opening the immediate packaging: use immediately.

Do not use this veterinary medicinal product after the expiry date which is stated on the packaging after Exp. The expiry date refers to the last day of that month.

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.

14. Marketing authorisation numbers and pack sizes

Vm 46608/3003

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

Each package includes disinfectant wipes moistened with 65% v/v isopropyl alcohol solution (2.4 ml/wipe) to clean teats.

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic
tel: +420 517 318 911
email: reklamace@bioveta.cz

<Local representatives< and contact details to report suspected adverse reactions>:>
To be completed nationally (if applicable).

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder. >

Gavin Hall
Approved: 25 July 2024