PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON BOX OR BUCKET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepralock 2.6 g Intramammary Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 g intramammary syringe contains 2.6 g bismuth subnitrate.

3. PACKAGE SIZE

24 syringes (packed in boxes)
144 syringes (packed in bucket)

4. TARGET SPECIES

Cattle (dairy cows at drying off).

5. INDICATIONS

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.

The product has a dual tip nozzle. The cap of the syringe can be partially or fully removed.
The short tip option allows for a partial insertion technique so that the syringe only needs to be inserted in the teat end.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

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

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 01708/4640

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepralock

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

bismuth subnitrate: 2.6 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Cepralock 2.6 g Intramammary Suspension for Dry Cows

2. Composition

Each 4 g intramammary syringe contains:

Active substance:

bismuth subnitrate	2.6 g
(equivalent to bismuth	1.9 g)

White to slightly yellow, homogeneous 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 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 lactating cows. See special warnings.
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 recognized tests for the detection of sub-clinical mastitis or bacteriological 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.
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 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:
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.
Bismuth salts have been associated with hypersensitivity reactions. People with known hypersensitivity to bismuth salts should avoid contact with the 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:
As the veterinary medicinal product is not absorbed following intramammary infusion, the veterinary medicinal product 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 indicated for use in dry cows. 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

None known.

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 using the contact details at the end of this leaflet, or via your national reporting system:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

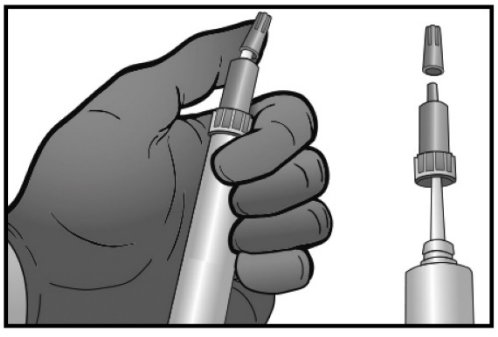
Intramammary use.
Infuse the content of one syringe of the veterinary medicinal product into each udder quarter immediately after the last milking of the lactation (at drying off).

9. Advice on correct administration

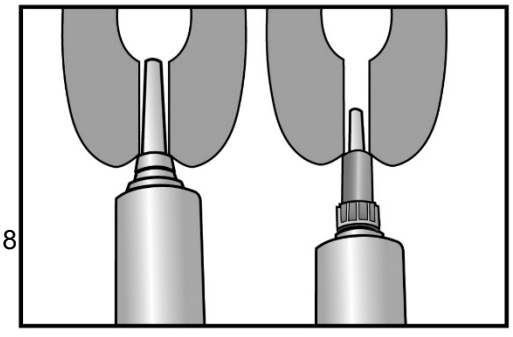
Do not use the veterinary medicinal product if you notice broken caps or any other visible signs of deterioration.

The veterinary medicinal product has a dual tip nozzle. 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.
Short tip option: The short tip option allows for a partial insertion technique so that the syringe only needs to be inserted in the teat end.
Long tip option: The long tip option may be used for treatment convenience for example to prevent the tip from flipping out due to a moving or nervous cow.

Step 1: Removal of the breakable cap



Step 2: Long or short tip insertion



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 in order to reduce the risk of post-infusion mastitis.

It is essential that the teat is thoroughly cleaned with the alcoholic disinfectant wipes provided. The teats should be wiped until there is no visible dirt collected on the wipe. 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.

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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 01708/4640
Pack sizes:
Carton box of 24 syringes and alcoholic disinfectant wipes.
Plastic bucket of 144 syringes and alcoholic 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:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ, UK

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

Contact details to report suspected adverse reactions:
UK(GB)
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

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

17. Other information

POM-V Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 11 March 2025