ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton or Bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepralock 2.6 g Intramammary Suspension for Dry Cows

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 g intramammary syringe contains 2.6 g bismuth subnitrate.

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

24 syringes (packed in boxes)

144 syringes (packed in bucket)

5. TARGET SPECIES

Cattle (dairy cows at drying-off).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramammary use.
Read the package leaflet before 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.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4640

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

'QR code to be included' + >URL<

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepralock 2.6 g Intramammary Suspension for Dry Cows

bismuth subnitrate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

bismuth subnitrate: 2.6 g

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMERS OF DOSES

4 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Cepralock 2.6 g Intramammary Suspension for Dry Cows

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepralock 2.6 g Intramammary Suspension for Dry Cows

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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.

4. INDICATION(S)

Prevention of new intramammary infections throughout the dry period.

In cows considered likely to be free of sub-clinical mastitis, the product can be used on its own in dry cow management and mastitis control.

5. CONTRAINDICATIONS

Do not use the 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 known cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle (dairy cows at drying-off).

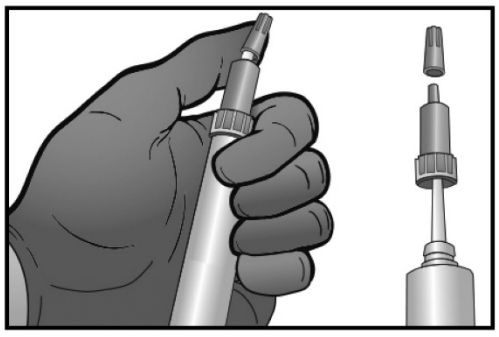
8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For intramammary use only.
Infuse the content of one syringe of the product into each udder quarter immediately after the last milking of the lactation (at drying off).

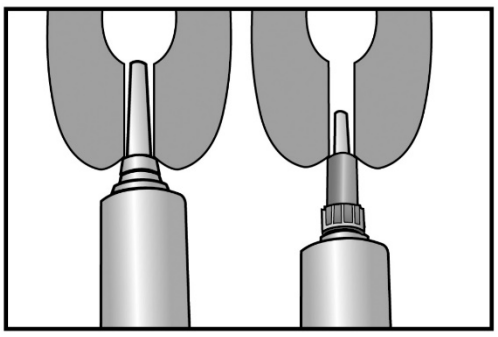
9. ADVICE ON CORRECT ADMINISTRATION

The 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 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 product may be warmed to room temperature in a warm environment, to aid syringeability.

10. WITHDRAWAL PERIOD(S)

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.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Selection of cows for treatment with the 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 warnings for use in animals:
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 product, because the product does not have antimicrobial activity.
Do not administer any other intramammary product following administration of the product.
In cows that may have sub-clinical mastitis, the 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 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. If you know that you are allergic to bismuth salts, avoid using this product.
If you develop symptoms following exposure, you should 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 product is not absorbed following intramammary infusion, the product can be used in pregnant animals. At calving, the seal may be ingested by the calf. Ingestion of the product by the calf is safe and produces no adverse effects.

Lactation:

The 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 (symptoms, emergency procedures, antidotes):

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

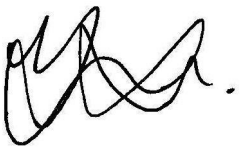
Dispose waste material (including used seal) in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package 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.



Approved: 09 April 2021