ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

24 – 60 – 120 SYRINGE CARTONS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK - BOVISEAL 2.6 g intramammary suspension for cattle (dairy cows)
Italy, Spain - EASISEAL 2.6 g intramammary suspension for cattle (dairy cows)
France - MAMISEAL 2.6 g intramammary suspension for cattle (dairy cows)

Bismuth subnitrate, heavy

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4g intramammary syringe contains:
Active substance: Bismuth subnitrate, heavy 2.6g

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

24 syringes
60 syringes
120 syringes

5. TARGET SPECIES

Cattle (Dairy Cows)

6. INDICATION(S)

The product is indicated for the prevention of new intramammary infections throughout the dry period.

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Meat: Zero days.
Milk: Zero hours.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

None.

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

Waste disposal: read the 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

Continental Farmaceutica
Rue Laid Burniat, 1
1348 Louvain-la-Neuve
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 41966/4001

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK - BOVISEAL 2.6 g intramammary suspension for cattle (dairy cows)
Italy, Spain - EASISEAL 2.6 g intramammary suspension for cattle (dairy cows)
France - MAMISEAL 2.6 g intramammary suspension for cattle (dairy cows)

Bismuth subnitrate, heavy.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 4g intramammary syringe contains:
Active substance: Bismuth subnitrate, heavy 2.6g

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

4 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use.

5. WITHDRAWAL PERIOD(S)

Meat: 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:
UK - Boviseal 2.6 g intramammary suspension for cattle (dairy cows)
Italy, Spain - EASISEAL 2.6 g intramammary suspension for cattle (dairy cows)
France - MAMISEAL 2.6 g intramammary suspension for cattle (dairy 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:

Continental Farmaceutica
Rue Laid Burniat, 1
1348 Louvain-la-Neuve
Belgium

Manufacturer responsible for batch release:

Cross Vetpharm Group Ltd
Dublin 24
IRELAND

Haupt Pharma Latina S.r.l
SS-156 Km 47,600
04100 Borgo San Michele (LT)
ITALY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK - BOVISEAL 2.6 g intramammary suspension for cattle (dairy cows).
Italy, Spain - EASISEAL 2.6 g intramammary suspension for cattle (dairy cows)
France - MAMISEAL 2.6 g intramammary suspension for cattle (dairy cows)

Bismuth subnitrate, heavy

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

The product is a greyish white, smooth, unctuous cream.

Each 4g intramammary syringe contains:
Active substance: Bismuth subnitrate, heavy 2.6g

4. INDICATIONS

The product is indicated for the prevention of new intramammary infections throughout the dry period.
The non-antibiotic dry cow treatment prevents new intramammary infections throughout the dry period with a zero milk and meat withdrawal period.
It is recommended that the product can be used as part of a herd approach to dry cow management and mastitis control. Cows considered likely to be free of subclinical mastitis

can be given the product at drying off. Other animals should be managed in accordance with an approved mastitis control plan or specific veterinary advice.
Selection of cows for treatment 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 subclinical mastitis or bacteriology sampling.
As a guide, where individual cell counts are available, cows with an average cell count less than 200,000 cells/ml may be given the product. A minor increase in cell count during the last 4 weeks before drying off is normal and may be ignored.

5. CONTRAINDICATIONS

Do not use alone in cows with subclinical mastitis at drying off.
Do not use in cows with clinical mastitis at drying off.
Do not use in the lactating cow. If lactating cows are accidentally infused , a small (up to 2-fold) transient rise in somatic cell count may be observed, but the seal can easily be stripped out manually and no additional precautions are necessary.
Do not administer any other intramammary product following the administration of the product.
Do not use in known cases of hypersensitivity to bismuth subnitrate or any of the excipients.

6. ADVERSE REACTIONS

None known. If you notice any side effects, or you think that the medicine has not worked, please inform your veterinary surgeon

7. TARGET SPECIES

Cattle (dairy cows).

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

For intramammary use only.

Dosage:
One syringe into each udder quarter immediately after the last milking of the lactation (at drying off). Do not massage the teat or udder after infusion.

Administration:
- Care must be taken not to introduce pathogens into the teat. It is essential that strict aseptic techniques are used for the infusion of the product as it possesses no antimicrobial activity. Failure to follow these recommendations can lead to serious cases of post-infusion mastitis and even death.
- All teats need to be thoroughly cleansed and disinfected prior to infusion of the product. Ensure sufficient time is allocated to treat each animal and do not combine this with other husbandry activities.
- Ensure animals are appropriately restrained in hygienic conditions. Keep syringes clean and DO NOT immerse in water.
- A separate pair of clean disposable gloves should be worn for the treatment of each cow.
- Start with a visibly clean, dry teat and udder. If teats are obviously dirty then clean off dirt from teats only, with moistened disposable paper towels and dry thoroughly. Dip teats in

a rapid-acting pre-dip, leave for 30 seconds, then wipe each teat completely dry with separate disposable paper towels. Strip fore milk into a strip cup and discard.
- Thoroughly disinfect the whole surface of the teat with a disposable spirit/alcohol soaked swab. Studies indicate that the most effective means of teat cleaning involves the use of swabs freshly prepared from clean dry cotton wool soaked in surgical spirit (or the equivalent). If this is not available, then the supplied sterile swabs can be used. Clean the teats furthest away from you first, to avoid contaminating clean teats
- Gently scrub each teat end with new individual, disposable, spirit/alcohol swabs, until both teat end and swab are visibly clean.
- Remove the cap from the intramammary tube, being careful not to touch the nozzle. Infuse the contents of the syringe into the teat avoiding contaminating the teat end. Infuse teats in the opposite order to cleaning i.e. treat the quarters closest to you first. Do not massage the product into the udder.
- Apply a post-milking teat disinfectant and confine the treated cows to a yard where they should stand for at least 30 minutes to allow the teat canal to close.

At calving ingestion of the product by the calf is safe and produces no adverse effects.

9. ADVICE ON CORRECT ADMINISTRATION

Advice to Herdsmen
It is important that you read the instructions before using this product.
Great care should be taken in maintaining cleanliness when administering the product in order to reduce the risk of potentially fatal post-infusion mastitis.
Full advice on teat cleaning technique prior to tubing is included in the instructions and should be followed.

10. WITHDRAWAL PERIOD(S)

Meat: 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 intramammary syringe and the carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special precautions 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 antibacterial therapy is instituted.

Cows considered likely to be free of subclinical mastitis should be given the veterinary medicinal product at drying off according to the criteria below. Other animals should be managed in accordance with an approved mastitis control plan or specific veterinary advice.

For practical purposes, selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of subclinical mastitis or bacteriological sampling. It is particularly important that, prior to treatment, an individual cell count be obtained from any cow with a history of clinical mastitis during the previous lactation. As a guide, cows with average cell counts less than 200,000 cells/ml before drying off may be given the veterinary medicinal product. A minor increase (cell count up to 250,000 cells/ml) during the last 4 weeks before drying off is normal and may be ignored. In case of doubt, veterinary advice should be sought.

In cows that may have sub-clinical mastitis, this product may be used following administration of a suitable dry cow antibiotic treatment to the infected quarter.

To reduce the risk of contamination, do not immerse the syringe in water.
For single use only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Avoid contact with skin or eyes.
Should skin or eye contact occur, wash the affected area thoroughly with water.
If irritation persists, seek medical advice and show this label to the doctor.
If you know that you are allergic to bismuth salts, avoid using this product.
Wash hands after use.

Pregnancy:
As the product is not absorbed following infusion, the product can be used in pregnant animals.

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

Dispose of any unused product, seal stripped from an animal at calving or waste material in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed at the end of the procedure.

15. OTHER INFORMATION

Most of the seal comes out at the first stripping or suckling after calving, but small amounts may occasionally be seen for a few days as flecks on the filter. The product can be differentiated from mastitis by its texture.
Twice the recommended dose has been administered to cows with no clinical adverse effects.
Under cold conditions the product may be warmed to room temperature in a warm environment, to aid syringeability.
After calving, the following steps are recommended for the effective removal of the product to minimise residual product entering the milking machine. The milking machine should not be used to remove the product from the teat.
1. Pinch the teat at the top and strip quarter 10-12 times prior to first milking.
2. Strip foremilk and check for residual product for first few milkings.

3. Inspect mastitis filters and milk sock for evidence of residual product after every milking.

Boxes of 24, 60 and 120 syringes.

Not all pack sizes may be marketed.

Approved: 08 November 2017