PARTICULARS TO APPEAR ON THE OUTER PACKAGE (24, 60 & 120 syringe packs)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mastiseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (IE, UK)
Boviseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (DE, PL, IT, NL, ES, AT, BE, CZ, EE, EL, HU, LT, LV, PT, SK)
Boviseal Intramammary Suspension for Cattle (Dry Cow) (FR)
Boviseal vet 2.6 g Intramammary Suspension for Cattle, Dry Cow (FI)
Boviseal (DK)
bismuth subnitrate, heavy

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Intramammary suspension.

4. PACKAGE SIZE

24 x 4 g
60 x 4 g
120 x 4 g

5. TARGET SPECIES

Cattle, (dairy cattle at the end of lactation)

6. INDICATION(S)

Uses:
The veterinary medicinal product is indicated for the prevention of new intramammary infections throughout the dry period in cattle. This results in a reduction in the incidence of subclinical mastitis in cows at calving, and of clinical mastitis in the dry period and the subsequent lactation (for at least 60 days after calving).
It is recommended that the veterinary medicinal product be used as part of a herd approach to dry cow management and mastitis control.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

Administration:
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 and disinfected, with surgical spirit or alcohol-impregnated wipes as the product possesses no antimicrobial activity.
Allow the teat to dry prior to infusion. Infuse aseptically and take care to avoid contamination of the intramammary syringe nozzle.
Insert nozzle into the teat and apply gentle and continuous pressure until the paste is expressed. Do not massage the teat or udder after infusion of the product.
Following infusion it is advisable to use an appropriate teat dip or spray.
At calving, the seal may be stripped out of the teat by hand or may be ingested by the calf.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications, warnings: Do not use in the lactating cow.
Do not use in cases of known hypersensitivity to the active substance or any of the excipients.
Do not use in cows with suspected or confirmed mastitis at drying off. If lactating cows are accidentally infused the seal can easily be stripped out manually and no additional precautions are needed.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only.

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

Cross Vetpharm Group Limited,
Broomhill Road, Tallaght, Dublin 24, Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mastiseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (IE, UK)
Boviseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (DE, PL, IT, NL, ES, AT, BE, CZ, EE, EL, HU, LT, LV, PT, SK)
Boviseal Intramammary Suspension for Cattle (Dry Cow) (FR)
Boviseal vet 2.6 g Intramammary Suspension for Cattle, Dry Cow (FI)
Boviseal (DK)
bismuth subnitrate, heavy

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

4g

4. ROUTE(S) OF ADMINISTRATION

For intramammary use.

5. WITHDRAWAL PERIOD

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

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

< MAH´s logo>

PACKAGE LEAFLET
Mastiseal/Boviseal 2.6 g Intramammary Suspension for Cattle, Dry Cow

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

Marketing authorisation holder and manufacturer responsible for batch release:

Cross Vetpharm Group Limited,
Broomhill Road, Tallaght, Dublin 24, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mastiseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (IE, UK)
Boviseal 2.6 g Intramammary Suspension for Cattle, Dry Cow (DE, PL, IT, NL, ES, AT, BE, CZ, EE, EL, HU, LT, LV, PT, SK)
Boviseal Intramammary Suspension for Cattle (Dry Cow) (FR)
Boviseal vet 2.6 g Intramammary Suspension for Cattle, Dry Cow (FI)
Boviseal (DK)
bismuth subnitrate, heavy

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

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

Greyish white, smooth oily suspension

4. INDICATION(S)

For the prevention of new intramammary infections throughout the dry period. This results in a reduction in the incidence of subclinical mastitis in cows at calving, and of clinical mastitis in the dry period and the subsequent lactation (for at least 60 days after calving). It is recommended that the veterinary medicinal product be used as part of a herd approach to dry cow management and mastitis control.

5. CONTRAINDICATIONS

Do not use in the lactating cow.
Do not use in cases of known hypersensitivity to the active substance or any of the excipients.
Do not use in cows with suspected or confirmed mastitis at drying off.

6. ADVERSE REACTIONS

None known.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (dairy cattle at the end of lactation)

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

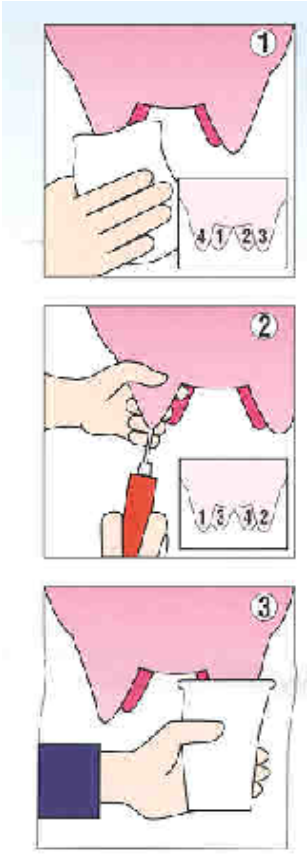
Dosage: For intramammary use. For single use only.
Infuse the content of one intramammary syringe into each udder quarter immediately after the last milking of the lactation (at drying off).

Administration: 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 and disinfected, with surgical spirit or alcohol-impregnated wipes as the product possesses no antimicrobial activity.
Allow the teat to dry prior to infusion. Infuse aseptically and take care to avoid contamination of the intramammary syringe nozzle.
Insert nozzle into the teat and apply gentle and continuous pressure until the paste is expressed. Do not massage the teat or udder after infusion of the product.
Following infusion it is advisable to use an appropriate teat dip or spray.

9. ADVICE ON CORRECT ADMINISTRATION

It is important that you read the instructions before using this product, and follow these simple steps to avoid introducing infections during administration:



1. Do not place individual syringes in warm/hot water during cold weather.
2. Dry cows off abruptly rather than gradually.
3. Great care should be taken in maintaining cleanliness when administering the product in order to reduce the risk of potentially fatal post-infusion mastitis.
4. Clean teat ends as thoroughly as possible with surgical spirit and leave to air dry. Do NOT use water with or without disinfectant.
5. Clean the two teats furthest away and then the two closest.
6. Ensure the teats are clean and dry before tubing.
7. Tube the teats in the opposite order to cleansing: i.e. the closest two teats first and then the two furthest away.
8. After tubing, dip teats in teat dip or spray with teat spray and leave cows standing in yard for at least half an hour to allow the teat canal to close.
9. Check cows regularly for signs of mastitis during the first week after drying off.

10. WITHDRAWAL PERIOD

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 and box after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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 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 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.

User Warnings: Wash hands after use.

Pregnancy: The veterinary medicinal product can be used during pregnancy. At calving, the seal may be stripped out of the teat by hand or 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 should not be administered during lactation. If accidentally used in a lactating cow the seal should be stripped out manually and no additional precautions are needed.

Interaction with other medicinal products and other forms of interaction: None known.

Overdose (symptoms, emergency procedures, antidotes): Twice the recommended dose has been administered to cows with no adverse effects.

For animal treatment only.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<[To be completed nationally]>

15. OTHER INFORMATION

Under cold conditions the product may be warmed to room temperature in a warm environment, to aid administration. Individual tubes must not be placed in warm water.

Pack sizes: 24 x 4 g, 60 x 4 g, 120 x 4 g.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:
<[To be completed nationally]>

Authorisation Number: xxx

Approved: 24/05/2017