ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbeseal dry cow 2.6 g intramammary suspension

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

24 intramammary syringes
60 intramammary syringes
120 intramammary syringes

5. TARGET SPECIES

Cattle (dairy cows at drying-off)

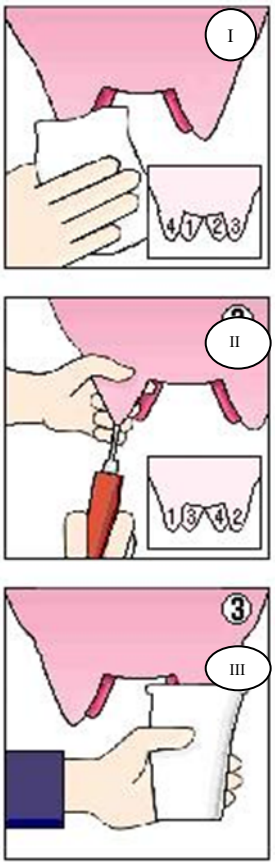
6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For intramammary use only.
Dosage:
One intramammary 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:
Aseptic intramammary infusion must be employed when administering this product.
Under cold conditions the product may be warmed to room temperature in a warm environment, to aid syringeability.

See images for correct administration.



8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat: zero days.
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Contra-indications, warnings:
Do not use alone in cows with subclinical mastitis at drying off (see package leaflet (Special Warnings) for more information).

Do not use in cows with clinical mastitis at drying off.

Do not use in the lactating cow.

Do not administer any other intramammary product following the administration of the product.
Use syringe only once.

This product may cause skin and eye irritation.
Wash hands after 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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4092

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbeseal dry cow 2.6 g intramammary suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

2.6g Bismuth subnitrate, heavy

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

4 g

4. ROUTE(S) OF ADMINISTRATION

For intramammary use only.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat: zero days
Milk: zero hours

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

(UK only:- Do not immerse in water
Do not massage the Udder after treatment
Use Syringe only once
Wash hands after Use
To be supplied only on Veterinary Prescription
Keep out of reach of children
Vm 42058/4092
POM-V)

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Orbeseal dry cow 2.6g intramammary suspension

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturers responsible for batch release:
Cross Vetpharm Group Ltd,
Dublin 24
IRELAND

Haupt Pharma Latina S.r.l
Borgo san Michele (LT)
ss 156km50 – Latina
ITALY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbeseal Dry cow 2.6 g intramammary suspension

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

The product is a greyish white, smooth, unctuous suspension. It is presented in intramammary syringes each containing 4 g intramammary suspension containing 2.6 g Bismuth subnitrate, heavy, in a mineral oil vehicle.

4. INDICATION(S)

The product is indicated for the prevention of new intramammary infections throughout the dry period.
The product prevents new intramammary infections by producing a physical barrier against the entry of bacteria.
In cows considered likely to be free of subclinical mastitis, the product can be used on its own in dry cow management and mastitis control.

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 known cases of hypersensitivity to the active substance or to any of the excipients
See section 12, Pregnancy and lactation.

6. ADVERSE REACTIONS

Acute mastitis has been reported very rarely after use of this product, primarily due to poor infusion technique and lack of hygiene. Please refer to sections “Dosage for each species, route(s) and method of administration” and “Special warning(s)” regarding the importance of aseptic technique.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.

7. TARGET SPECIES

Cattle (dairy cows at drying-off)

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

For intramammary use only.

Dosage: One intramammary 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.

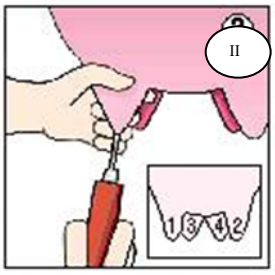
1. All teats need to be thoroughly cleansed and disinfected prior to infusion of the product. Ensure sufficient time is allocated to treat each animal and do not combine this with other husbandry activities.

2. Ensure animals are appropriately restrained in hygienic conditions. Keep syringes clean and DO NOT immerse in water.

3. A separate pair of clean disposable gloves should be worn for the treatment of each cow.

4. 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.

5. 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. See image I.



6. Gently scrub each teat end with new individual, disposable, spirit/alcohol swabs, until both teat end and swab are visibly clean.

7. Remove the cap from the intramammary tube, being careful not to touch the nozzle.

8.Grip the teat base firmly between your fingers at the junction with the udder. Turn the teat to a slight angle. Infuse the contents of the syringe into the bottom portion of the teat below where you are pinching the teat avoiding contaminating the teat end. Infuse teats in the opposite order to cleaning i.e. treat the quarters closest to you first. See image II. Do not massage the product into the udder.

9. 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. See image III.

9. ADVICE ON CORRECT ADMINISTRATION

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.

Under cold conditions the product may be warmed to room temperature in a warm environment, to aid syringeability.

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 carton and label after EXP. 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 recognised tests for the detection of subclinical mastitis or bacteriology sampling.

Special precautions for use in animals:
In cows that may have subclinical mastitis, the product may be used following administration of a suitable dry cow antibiotic treatment to the infected quarter. As with all dry cow intramammary treatments, 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 antibiotic therapy is instituted.
To reduce the risk of contamination, do not immerse syringes in water.
Use 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 “Adverse reactions”), it is crucial to follow the aseptic technique of administration described in section “Dosage for each species, route(s) and method of administration”

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.
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 and lactation:

As the product is not absorbed following infusion it can be used in pregnant animals. At calving ingestion of the product by the calf is safe and produces no adverse effects.

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.
Interaction with other medicinal products and other forms of interaction:

In clinical trials, the compatibility of the product has only been shown with a cloxacillin-containing dry cow preparation.
Do not administer any other intramammary product following the administration of the product.

Overdose

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 MATERIAL, IF ANY

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

November 2020

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.
After calving, the following steps are recommended for the effective removal of the productto 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.

Available in boxes of 24, 60 and 120 intramammary syringes

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

Approved 23 April 2021