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 AND OTHER SUBSTANCES

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

3. PACKAGE SIZE

24 intramammary syringes
60 intramammary syringes
120 intramammary syringes

4. TARGET SPECIES

Cattle (dairy cow at drying-off)

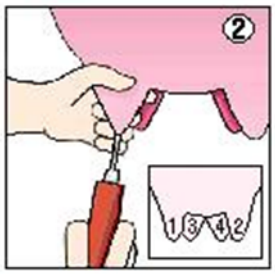
5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

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

See images for correct administration.



7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the syringe in the outer carton.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5106

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Syringe label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbeseal dry cow 2.6 g

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

2.6 g Bismuth subnitrate, heavy

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

4 g

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbeseal Dry cow 2.6 g intramammary suspension for cattle

2. COMPOSITION

Each 4 g intramammary syringe contains:

Active substance:
Bismuth subnitrate, heavy 2.6 g
(equivalent to Bismuth, heavy 1.858 g)

Excipients:
Liquid paraffin
Aluminium Di Tri stearate
Silica, colloidal anhydrous

Greyish white, smooth, unctuous intramammary suspension.

3. TARGET SPECIES

Cattle (dairy cow at drying-off)

4. INDICATIONS FOR USE

The veterinary medicinal product is indicated for the prevention of new intramammary infections throughout the dry period.
The veterinary medicinal 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 veterinary medicinal 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 cases of hypersensitivity to the active substance or to any of the excipients
See section 6, Pregnancy and lactation.

6. SPECIAL WARNING(S)

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 recognised tests for the detection of subclinical mastitis or bacteriology sampling.

Special precautions for safe use in the target species:
In cows that may have subclinical mastitis, the veterinary medicinal 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 veterinary medicinal 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 7 “Adverse events”), it is crucial to follow the aseptic technique of administration described in section 8 “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 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.
If irritation persists, seek medical advice and show this label to the doctor.
People with known hypersensitivity to bismuth salts should avoid contact with the veterinary medicinal product.
Wash hands after use.

Pregnancy:
The veterinary medicinal product is not absorbed following intramammary infusion.
Can be used during pregnancy. 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:
Do not use during lactation. 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 the veterinary medicinal product has only been shown with a cloxacillin-containing dry cow preparation.
Do not administer any other intramammary product following the administration of the veterinary medicinal product.

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

7. ADVERSE EVENTS

Cattle (dairy cow at drying-off).

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Acute mastitis[1].

[1]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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 or its local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

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.

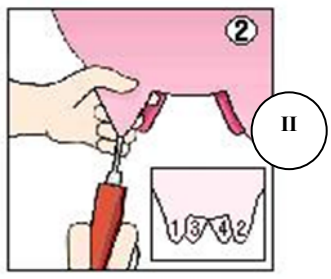
Administration:
Care must be taken not to introduce pathogens into the teat. It is essential that strict aseptic techniques are used for the infusion of the veterinary medicinal product as it possesses no antimicrobial activity. Failure to follow these recommendations can lead to serious cases of post-infusion mastitis and even death.

1. All teats need to be thoroughly cleansed and disinfected prior to infusion of the veterinary medicinal 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 cleaning 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 veterinary medicinal 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 veterinary medicinal product.

Great care should be taken in maintaining cleanliness when administering the veterinary medicinal 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 veterinary medicinal 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 carton and 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.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5106

Available in boxes of 24, 60 and 120 intramammary syringes
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. CONTACT DETAILS

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
Strada Statale 156 Dei Monti Lepini Km 47600
Latina
04100
ITALY

17. 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 veterinary medicinal product can be differentiated from mastitis by its texture.

After calving, the following steps are recommended for the effective removal of the veterinary medicinal product to minimise residual product entering the milking machine. The milking machine should not be used to remove the veterinary medicinal 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.

Approved 15 September 2023