

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON/BUCKET}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroseal 2.6g Intramammary Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4g intramammary syringe contains:

Active substance:

Bismuth subnitrate, heavy 2.6g

3. PACKAGE SIZE

24 syringes
60 syringes
120 syringes

4. TARGET SPECIES

Cattle (dairy cows)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat & offal: zero days

Milk: zero hours

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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 OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

14. MARKETING AUTHORISATION NUMBER

Vm 02000/3015

15. MANUFACTURER’S BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE
PACKAGING UNITS**

{SYRINGE/LDPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Noroseal

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Bismuth subnitrate, heavy 2.6g per intramammary syringe

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

<Exp {mm/yyyy}>

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Noroseal 2.6g Intramammary Suspension for Cattle

2. Composition

Each 4g intramammary syringe contains:

Active substance:

Bismuth subnitrate, heavy 2.6g

Light brown suspension

3. Target species

Cattle (dairy cows).

4. Indications for use

Prevention of new intramammary infections throughout the dry period.

In cows considered likely to be free of sub-clinical mastitis, the veterinary medicinal product may be suitable for use on its own in dry cow management for mastitis control.

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 sub-clinical mastitis such as bacteriological sampling.

5. Contraindications

Do not use in lactating cows. Do not use the veterinary medicinal 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 cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:

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.

Since the veterinary medicinal product does not have antimicrobial activity, in order to minimise the risk of acute mastitis due to poor technique and lack of hygiene (see section 7), it is crucial to follow the aseptic technique of administration described in section 9.

Do not administer any other intramammary product following administration of the product.

In cows that may have sub-clinical mastitis, the veterinary medicinal product may be used following administration of an appropriate dry cow antibiotic treatment to the infected quarter.

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 immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to bismuth salts should avoid contact with the veterinary medicinal product.

Wash hands after use.

Pregnancy:

As the veterinary medicinal product is not systemically 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:

If accidentally used in a lactating cow, a transient rise in somatic cell count (up to 2-fold) 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.

Overdose:

Twice the recommended dose has been administered to cows without any clinical adverse effects.

Major incompatibilities:

None known.

7. Adverse Events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Acute mastitis ¹
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¹ Primarily due to the poor infusion technique and lack of hygiene. See section 9 regarding the importance of aseptic technique.

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

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Intramammary use.

Infuse the contents of one syringe of the veterinary medicinal product into each udder quarter immediately after the last milking of the lactation (at drying off).

9. Advice on correct administration

Do not massage the teat or udder after infusion of the veterinary medicinal product.

Care must be taken on aseptic technique 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. The teats should be wiped until the wipes are no longer visibly dirty. 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 veterinary medicinal product may be warmed to room temperature in a warm environment to aid syringeability.

10. Withdrawal periods

Meat & 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 carton 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.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 02000/3015

Cartons of 24 or 60 syringes, or bucket of 120 syringes including 24, 60 or 120 individually wrapped teat cleaning towels.

Not all pack sizes may be marketed

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

(UK)

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

Manufacturer responsible for batch release:

(NI)

Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

(UK)

Norbrook Laboratories Limited
105 Armagh Road, Newry
Co. Down, Northern Ireland
BT35 6PU

Norbrook Laboratories Limited
Station Works, Newry,
Co. Down, Northern Ireland,
BT35 6JP

17. Other information

POM-VPS

FOR ANIMAL TREATMENT ONLY

Gavin Hall

Approved: 11 February 2026