

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**{CARTON/BUCKET}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Noroseal 2.6g Intramammary Suspension for Cattle  
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**

Cartons of 24 or 60 syringes, or bucket of 120 syringes

**5. TARGET SPECIES**

Dairy Cattle

**6. INDICATION(S)**

Prevention of new intramammary infections throughout the dry period.

In cows considered likely to be free of sub-clinical mastitis, the 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.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramammary use.  
Read the package leaflet before use

**8. WITHDRAWAL PERIOD (S)**

**WITHDRAWAL PERIODS:**

Meat & offal: zero days  
Milk: zero hours

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use

**10. EXPIRY DATE**

Exp.: mm/yyyy

**11. SPECIAL STORAGE CONDITIONS**

No special precautions for storage.

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

**13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable**

For Animal Treatment Only.

UK Only

POM-V

To be supplied only on veterinary prescription.

Vm: 02000/4361

**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**

**(EU)**

Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

**(UK)**

Norbrook Laboratories Limited,  
Station Works,  
Camlough Road,  
Newry,  
County Down,  
Northern Ireland  
BT35 6JP

**16. MARKETING AUTHORISATION NUMBER(S)**

VM 02000/4361

**17. MANUFACTURER'S BATCH NUMBER**

BN.:

D.O.M.:

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

{NATURE/TYPE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Noroseal 2.6g Intramammary Suspension for Cattle  
bismuth subnitrate, heavy

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Bismuth subnitrate, heavy 2.6g per intramammary syringe

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

4g

**4. ROUTE(S) OF ADMINISTRATION**

Intramammary use.  
Read the package leaflet before use.

**5. WITHDRAWAL PERIOD (S)**

**WITHDRAWAL PERIODS:**

Meat & offal: zero days  
Milk: zero hours

**6. BATCH NUMBER**

<Batch><Lot> {number}

**7. EXPIRY DATE**

<EXP {month/year}>

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**PACKAGE LEAFLET FOR:  
Noroseal 2.6g intramammary suspension for Cattle**

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

Marketing authorisation holder:

(EU)  
Norbrook Laboratories (Ireland) Limited  
Rossmore Industrial Estate  
Monaghan  
Ireland

(UK)  
Norbrook Laboratories Limited,  
Station Works  
Camlough Road,  
Newry,  
County Down,  
Northern Ireland  
BT35 6JP

Manufacturer responsible for batch release:

(EU)  
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
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**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Noroseal 2.6g Intramammary Suspension for Cattle  
bismuth subnitrate, heavy

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

Each 4g intramammary syringe contains:

Active substance:  
Bismuth subnitrate, heavy 2.6g

Light brown suspension

#### **4. INDICATION(S)**

Prevention of new intramammary infections throughout the dry period.

In cows considered likely to be free of sub-clinical mastitis, the 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 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. ADVERSE REACTIONS**

'If you notice any side effects or you think that the medicine has not worked, please inform your veterinary surgeon.'

#### **7. TARGET SPECIES**

Dairy Cattle

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

Intramammary use.

Infuse the contents of one syringe of the 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 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 product may be warmed to room temperature in a warm environment to aid syringeability.

## 10. **WITHDRAWAL PERIOD (S)**

Meat & offal: zero days

Milk: zero hours

## 11. **SPECIAL STORAGE PRECAUTIONS**

No special precautions for storage.

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the label and carton after "EXP"

## 12. **SPECIAL WARNINGS**

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.

It is important to observe strict aseptic technique for the administration of the product, because the product does not have antimicrobial activity. Do not administer any other intramammary product following administration of the product.

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

Pregnancy:

As the 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.

In clinical trials, the compatibility of the product has only been shown with a cloxacillin-containing dry cow preparation.

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

Incompatibilities:

None known.

**Operator warning:**

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 leaflet to the doctor.

If you know that you are allergic to bismuth salts, avoid using this product.

Wash hands after use.

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

July 2019

**15. OTHER INFORMATION**

**PACKAGE QUANTITIES:**

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



**FURTHER INFORMATION:**

For Animal Treatment Only

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 26 July 2019