Summary of Product Characteristics

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sureseal 2.6g Intramammary Suspension for Cattle (IE, FR, UK)
Noroseal 2.6g Intramammary Suspension for Cattle (BE, ES, IT, NL, PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4g Intramammary syringe contains:

Active substance:

Bismuth subnitrate, heavy 2.6g

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension
Light brown suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (dairy cows)

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

See section 4.7. 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.

4.4 Special warnings

None

4.5 Special precautions for use

(i) Special precautions for use in animals

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 product does not have antimicrobial activity, in order to minimise the risk of acute mastitis due to poor infusion technique and lack of hygiene (see section 4.6), it is crucial to follow the aseptic technique of administration described in section 4.9.
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 a suitable dry cow antibiotic treatment to the infected quarter.

(ii) 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 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.

4.6 Adverse reactions (frequency and seriousness)

Acute mastitis has been reported very rarely after use of this product, primarily due to the poor infusion technique and lack of hygiene. Please refer to sections 4.5 and 4.9 regarding the importance of aseptic technique.

The frequency for adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

Intramammary use.
Infuse the content of one syringe of the product into each udder quarter immediately after the last milking of the lactation (at drying off). Do not massage the teat or udder after infusion of the product.

Care must be taken not to introduce pathogens into the teat in order to reduce the risk of post-infusion mastitis (aseptic technique).

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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal periods

Meat & offal: zero days
Milk: zero hours

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Various products for teats and udder
ATCvet code: QG52X

5.1 Pharmacodynamic properties

Infusion of the product into each udder quarter produces a physical barrier against the penetration of bacteria thereby reducing the incidence of ascending intramammary infections during the dry period.

5.2 Pharmacokinetic particulars

Bismuth subnitrate, heavy is not systemically absorbed from the mammary gland, but resides as a seal in the teat until physically removed (Shown in cows with a dry period up to 100 days).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium di-/tri stearate
Povidone, iodinated
Liquid Paraffin

6.2 Major Incompatibilities

None known

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

No special precautions for storage.

6.5 Nature and composition of immediate packaging

Low density polyethylene syringe with a smooth tapered hermetically sealed nozzle.
Pack sizes:

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

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON/BUCKET}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sureseal 2.6g Intramammary Suspension for Cattle
bismuth subnitrate, heavy

2. STATEMENT OF ACTIVE AND OTHER 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.

(National legal category to be included here)

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN.:
D.O.M.:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{SYRINGE/LDPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sureseal 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:
Sureseal 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;
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sureseal 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

Acute mastitis has been reported very rarely after use of this product, primarily due to the poor infusion technique and lack of hygiene. Please refer to section 9 regarding the importance of aseptic technique.

The frequency for adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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.
Since the product does not have antimicrobial activity, in order to minimise the risk of acute mastitis due to poor infusion technique and lack of hygiene (see section 6), 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 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

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