ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4 g intramammary syringe contains:

Active substance:

Bismuth subnitrate, heavy 2.6 g

Excipients:

Qualitative composition of excipients and other constituents
Aluminium di-/tri Stearate
Povidone, iodinated
Liquid Paraffin

Light brown suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dairy cows).

3.2 Indications for use for each target species

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 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 sub-clinical mastitis such as bacteriological sampling.

3.3 Contraindications

See section 3.7. 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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 infusion technique and lack of hygiene (see section 3.6), it is crucial to follow the aseptic technique of administration described in section 3.9.
Do not administer any other intramammary product following administration of the veterinary medicinal product.
In cows that may have sub-clinical mastitis, the veterinary medicinal product may be used following administration of a suitable 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 and show the package leaflet or label to the physician.
People with known hypersensitivity to the active substance should avoid contact with the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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

[1] Primarily due to the poor infusion technique and lack of hygiene. See sections 3.5 and 3.9 regarding the importance of aseptic technique.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 veterinary medicinal 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.

3.8 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.

3.9 Administration routes and dosage

Intramammary use.
Infuse the content of one syringe of the veterinary medicinal 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 veterinary medicinal product may be warmed to room temperature in a warm environment to aid syringeability.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat & offal: zero days.
Milk: zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QG52X

4.2 Pharmacodynamics

Infusion of the veterinary medicinal 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.

4.3 Pharmacokinetics

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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 26/07/2013.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. (BE, IT, NL, PT, ES, UK)
Veterinary medicinal product not subject to prescription. (IE, FR)

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARTON/BUCKET}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sureseal 2.6 g Intramammary Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 g intramammary syringe contains:

Active substance:
Bismuth subnitrate, heavy 2.6 g

3. PACKAGE SIZE

24 syringes
60 syringes
120 syringes

4. TARGET SPECIES

Cattle (Dairy Cows).

5. INDICATIONS

For products not subject to veterinary prescription
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.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{SYRINGE/LDPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sureseal

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Bismuth subnitrate, heavy 2.6 g per intramammary syringe

3. BATCH NUMBER

Lot{number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Sureseal 2.6 g Intramammary Suspension for Cattle

2. Composition

Each 4 g intramammary syringe contains:

Active substance:
Bismuth subnitrate, heavy 2.6 g

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 and show the package leaflet or label to the physician.
People with known hypersensitivity to the active substance 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]

[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:{national system details}

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.

No special precautions for storage.
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. (BE, IT, NL, PT, ES, UK)
Veterinary medicinal product not subject to prescription. (IE, FR)

14. Marketing authorisation numbers and pack sizes

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. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland
Tel: +44 (0)28 3026 4435
E-mail: phvdept@norbrook.co.uk

(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:
(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

<Local representatives <and contact details to report suspected adverse reactions>:>

17. Other information

FOR ANIMAL TREATMENT ONLY