Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Multiject IMM Intramammary Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5g syringe contains:

Active Substances:

Procaine Benzylpenicillin	100,000	IU
Streptomycin Sulphate	100	mg
Neomycin Sulphate	100	mg
Prednisolone	10	mg

For a full list of excipients, see sction 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

Multiject IMM is indicated in the treatment of acute and subacute mastitis in lactating cows, caused by organisms sensitive to penicillin, streptomycin and neomycin therapy.

Sensitive organisms include:

Streptococcal species
Staphylococcus aureus
Escherichia coli

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special Precautions for Use in Animals

Before infusion, the teat should be thoroughly cleaned and disinfected and care should be taken to avoid contamination of the injector nozzle. Following infusion, it is advisable to use a teat dip or spray.

Special Precautions to be taken by the Person Administering the Medicinal Product to Animals

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross sensitivity to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.

2. Handle this product with great care to avoid exposure, taking all recommended precautions.

3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips and eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

Multiject IMM can be safely administered to pregnant or lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None.

4.9 Amounts to be administered and administration route

The contents of one syringe should be infused into each infected quarter via the teat canal immediately after milking, once daily for three consecutive days. Aseptic precautions should be observed at all times.

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

Not applicable.

4.11 Withdrawal period(s)

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption may only be taken from 96 hours (i.e. at the 8th milking) from the last treatment.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Combinations of antibacterials for intramammary use; Antibacterials and Corticosteroids.
ATCvet Code: QJ51RV01.

5.1 Pharmacodynamic properties

Procaine Benzylpenicillin exerts its effect on multiplying bacteria by interfering with the formation of the cell wall.

Streptomycin sulphate and Neomycin Sulphate are both aminoglycoside antibiotics which after penetration of the cell envelope bind to receptors on the 30s subunit of the ribosome. They induce misreading of the genetic code on the messenger ribonucleic acid (mRNA) template. Prednisolone is a glucocorticoid which has anti-inflammatory properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin
White Soft Paraffin

6.2 Major incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

A 7 ml single dose, sterile white polyethylene self-venting syringe containing an off-white oily suspension.

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

Any unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1988
Date of last renewal: 30 September 2008

10 DATE OF REVISION OF THE TEXT

January 2019