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 Substance:

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

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Intramammary suspension.
A white oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (milk cows).

4.2 Indications for use, specifying the target species

Indicated in the treatment of acute and subacute bovine mastitis in milking cows, accompanied by pain and inflammation caused by bacterial infection sensitive to penicillin, streptomycin and neomycin therapy.

4.3 Contraindications

None.

4.4 Special Warnings for each target species

No special warnings.

4.5 Special precautions for use

i Special precautions for use in animals

During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Protective gloves should be worn when infusing heifers, to avoid skin contact with the product.

Penicillins and cephalosporins may cause hypersensitivity following injection, inhalation, ingestion, or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions 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 skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

No known undesirable effects.

4.7 Use during pregnancy, lactation or lay

This product can be safely administered to cows during pregnancy or lactating. Also see warning in section 4.11 regarding withdrawal periods.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

The contents of one syringe should be infused gently 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

Milk for human consumption must not be taken from a cow during treatment. Milk for human consumption may only be taken from 108 hours 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 PROPERTIES

ATCvet Code: QJ51RV01

Pharmacotherapeutic group: Antibacterials for intramammary use, Combination of antibacterials for intramammary use, Combinations of antibacterials and other substances.

Pharmacodynamic properties:

Procaine Penicillin 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 Light
White Soft Paraffin

6.2 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 25ºC.
The syringe must only be used once. Part used syringes must be discarded.

6.5 Nature and composition of immediate packaging

White pre-filled 5g single dose intramammary syringes with a low density polyethylene barrel and white or yellow plunger, with white or yellow low density polyethylene end caps.

Available in packs of 24 single dose syringes.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4062

9. DATE OF FIRST AUTHORISATION

29th March 1985

10. DATE OF REVISION OF THE TEXT

July 2010