SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Magniject 25% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Contains Magnesium Sulphate Heptahydrate 25.0% w/v
(equivalent to Magnesium Sulphate anhydrous 12.21% w/v)

Excipients:
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection
A clear colourless/pale yellow solution for Injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and Sheep

4.2 Indications for use, specifying the target species

Indicated in the treatment of hypomagnesaemia in cattle and sheep

4.3 Contraindications

Do not administer intravenously.

4.4 Special Warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

None

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

Care should be taken to avoid accidental self-injection
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Can be safely administered during pregnancy and lactation

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Administer by subcutaneous injection only, observing aseptic technique.

Cattle : Up to 400 ml
Sheep: Up to 75 ml

Warm to body temperature before administration, and gently massage the site of injection. For subcutaneous injection only, observing aseptic precautions. Divide the total dose volume to be administered between 2 or more sites.

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

Not applicable.

4.11 Withdrawal period

Cattle			Sheep		
Meat	:	Zero Days	Meat	:	Zero Days
Milk	:	Zero Hours	Milk	:	Zero Hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Mineral supplements, Other mineral supplements, Magnesium

ATC Vet Code: QA12CC

5.1 Pharmacodynamic properties

When administered by subcutaneous injection the product corrects the ionic disturbance associated with hypomagnesaemia. Magnesium is an essential mineral involved in metabolism, muscle activity and nerve functions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid, Concentrated
Water for Injections

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

This product does not contain an antimicrobial preservative. Do not store above 25^{o}C.

Any solution remaining in the vial following withdrawal of the required dose should be discarded.

6.5 Nature and composition of immediate packaging

Marketed in either 400 ml Amber Type III glass vials sealed using black rubber wads and aluminium screw caps, or 400ml white polypropylene bottles sealed with grey bromobutyl bungs and aluminium caps.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4129

9. DATE OF FIRST AUTHORISATION

19th October 1994

10. DATE OF REVISION OF THE TEXT

July 2010