IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10999/045/001**
Case No: 7001151

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Norbrook Laboratories Limited

Station Works, **Camlough Road**, **Co. Down BT35 6JP**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Magniject 25% Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **01/10/2006**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Magniject 25% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Magnesium Sulphate Heptahydrate 25.0 % w/v

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep.

4.2 Indications for use, specifying the target species

Magniject is 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

Special precautions for use in animals

Warm to body temperature prior to administration.

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

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Magniject 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.

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

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

Not applicable.

4.11 Withdrawal Period(s)

Meat: zero days.
Milk: zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Magniject administered by subcutaneous injection corrects the ionic disturbance that results from hypomagnesaemia.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid
Water for Injection

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
This product is for single use only.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and composition of immediate packaging

Magniject, a clear colourless solution, is marketed in either 400 ml Amber Type III glass vials sealed with black rubber wads and aluminium screw caps, or 400 ml polypropylene containers sealed with bromobutyl bungs and aluminium caps.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/45/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2006

10 DATE OF REVISION OF THE TEXT

None.