1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Magniject 250 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Magnesium Sulphate Heptahydrate 250 mg

Excipients:

Qualitative composition of excipients and other constituents
Hydrochloric Acid
Water for Injection

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated in the treatment of hypomagnesaemia in cattle and sheep.

3.3 Contraindications

Do not administer intravenously.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Warm to body temperature prior to administration.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None.

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 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 and lactation:
The veterinary medicinal product can be safely administered during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Administer by subcutaneous injection only.
Cattle: Up to 400 ml
Sheep: Up to 75 ml

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

Not applicable.

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 and offal: zero days.
Milk: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QA12CC

4.2 Pharmacodynamics

The veterinary medicinal product administered by subcutaneous injection corrects the ionic disturbance that results from hypomagnesaemia.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product 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.

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 or household waste.

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

Norbrook Laboratories (Ireland) Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22664/030/001

8. DATE OF FIRST AUTHORISATION

01/10/1991

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

13/08/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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