

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Magnidown 25%w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Magnesium Sulphate Heptahydrate 25.0% w/v

Excipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle
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.

If accidental self-injection or ingestion occurs, seek medical advice immediately.

In case of eye or skin contact, rinse the affected area immediately with plenty of clean water.

Seek medical attention if irritation persists.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Magnidown 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. 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:
ATC Vet Code: QA12CC02

5.1 Pharmacodynamic properties

Magnesium is an essential mineral involved in metabolism, muscle activity and nerve function.

When administered by subcutaneous injection the product corrects the ionic disturbance associated with 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

6.4 Special precautions for storage

Do not store above 25°C.

This product does not contain an antimicrobial preservative.

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

6.5 Nature and composition of immediate packaging

400ml amber Type III glass vials sealed using black rubber wads and aluminium screw caps

400ml polypropylene containers sealed with bromobutyl bungs and aluminium caps.

Not all pack sizes may be marketed.

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
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4287

9. DATE OF RENEWAL OF AUTHORISATION

03 March 2010

10. DATE OF REVISION OF THE TEXT

September 2010