

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Magnesium Sulphate 25% Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Magnesium Sulphate Heptahydrate 25.0 % w/v

For a full list of excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep

4.2 Indications for use, specifying the target species

Magnesium Sulphate 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 Product to Animals

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Magnesium Sulphate 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: Nil. Animals intended for human consumption may be slaughtered following treatment.
Milk: Nil. Milk intended for human consumption may be taken from animals during treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid
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

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Magnesium Sulphate is marketed in 400 ml Amber Type III glass vials sealed with black rubber wads and aluminium screw caps.

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

None.

7 MARKETING AUTHORISATION HOLDER

Chem-Pharm Ltd.
Ballyvaughan
Co. Clare

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10823/16/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001