

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.

A clear colourless sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

It is indicated in the treatment of hypomagnesaemia and hypomagnesaemic tetany.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Administer with care particularly for very slow intravenous use. Intravenous injection should be given slowly and stopped at once if untoward symptoms occur. As intravenous administration of this product could cause death, this route should only be used by a veterinary surgeon. Use aseptic technique. Bring contents to body temperature in cold weather prior to administration. Massage the subcutaneous site of injection during administration and for a short period after.

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

This product may be used 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

Administration is by subcutaneous and/or slow intravenous injection.

The recommended dose rate is: up to 400ml.

The dosage required depends on the clinical condition/response of the animal being treated. When being administered by the intravenous route, the amount to use is left to the discretion of the veterinary practitioner.

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

The product is for treatment of acute deficiency in a life threatening situation and overdosage within the recommended guidelines is unlikely.

4.11 Withdrawal Period(s)

Meat: Nil.

Milk: Nil.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group; Magnesium Sulphate

ATC Vet Code; QA12CC02

5.1 Pharmacodynamic properties

Magnesium is an essential nutrient of low toxicity, its use is mainly for the correction of hypomagnesaemia.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Store below 25°C.

6.5 Nature and composition of immediate packaging

A 400 ml amber glass bottle with black rubber wad and aluminium screw cap.

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

None.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/37/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2001