SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Magnesium Sulphate Injection 50%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium Sulphate BP 50% w/v

3 PHARMACEUTICAL FORM

Sterile solution for parenteral use.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of magnesium deficiency where the oral route of administration may be inappropriate, which may be due to malabsorption syndromes, chronic alcoholism, malnutrition, severe diarrhoea or patients on total parenteral nutrition.

4.2 Posology and method of administration

Magnesium sulphate injection may be administered by intramuscular or intravenous routes. Since intramuscular (IM) injections are painful, involve multiple punctures, and have no therapeutic advantage over the intravenous route, IM therapy should be used only when peripheral venous access is impossible. For intravenous administration, a concentration of 20% or less should be used; the rate of injection not exceeding 1.5ml/minute of a 10% solution or its equivalent.

Dosage should be reduced in renal impairment.

Plasma magnesium concentrations should be monitored throughout therapy

<u>Adults</u>

The dosage should be individualised according to patient's needs and responses.

Mild magnesium deficiency

1g intramuscularly every 6 hours for 4 doses.

Severe magnesium deficiency

Up to 250mg/kg intramuscularly given within a period of 4 hours or 5g/litre of infusion solution intravenously over 3 hours.

Children

It is recommended that the solution be diluted to 20% w/v prior to intramuscular injection.

For intravenous administration, it is recommended in children and infants that magnesium sulphate be given as a 1% (10 milligrams per milliliter) solution intravenously over 1 hour. In severe conditions, it has been suggested to administer half of the dose during the first 15 to 20 minutes. Up to a 3% magnesium sulphate solution has been suggested for intravenous use in severe conditions.

Hypomagnesemia; Treatment and Prophylaxis
Neonates, magnesium sulfate 25 to 50 mg/kg IV every 8 to 12 hours for 2 to 3 doses
Children, magnesium sulfate 25 to 50 mg/kg IV every 4 to 6 hours for 3 to 4 doses; MAX single dose is 2000 mg.

Elderly

No special recommendations except in renal impairment.

4.3 Contraindications

Hypersensitivity to magnesium and it salts.
Magnesium sulphate is contraindicated in patients with heart block, myocardial damage or severe impaired renal function.

4.4 Special warnings and precautions for use

Magnesium sulphate must be used with caution in patients suspected of or known to have renal impairment.
Magnesium sulphate should not be used in hepatic coma if there is a risk of renal failure.
Parenteral magnesium salts should be used with caution in patients with myasthenia gravis.

Serum calcium levels should be routinely monitored in patients receiving magnesium sulphate.

4.5 Interaction with other medicinal products and other forms of interaction

Administer with caution to patients receiving digitalis glycosides. Effects of neuromuscular blocking agents may be enhanced. Magnesium sulphate should not be administered concomitantly with high doses of barbiturates, opioids or hypnotics due to the risk of respiratory depression.

Concomitant use of calcium channel blockers such as nifedipine or nimodipine may very rarely lead to a calcium ion imbalance and could result in abnormal muscle function.

The neuromuscular blocking effects of parenteral magnesium and aminoglycoside antibacterials may be additive.

4.6 Fertility, Pregnancy and lactation

Safety in human pregnancy and during breastfeeding has not been established, therefore, as with all drugs it is not advisable to administer magnesium sulphate during pregnancy or breastfeeding unless considered essential, and it must be administered under medical supervision.

Magnesium crosses the placenta. When used in pregnant women, foetal heart rate should be monitored and use within 2 hours of delivery should be avoided.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Hypersensitivity reactions.

Hypocalcaemia.

Hypermagnesaemia characterised by flushing, thirst, hypotension, drowsiness, nausea, vomiting, confusion, slurred speech, double vision, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, electrolyte/fluid abnormalities (hypophosphatemia, hyperosmolar dehydration), ECG changes (prolonged PR, QRS and QT intervals), bradycardia, cardiac arrhythmias, coma and cardiac arrest.

There is a risk of respiratory depression if magnesium sulphate is administered concomitantly with high doses of barbiturates, opioids or hypnotics (see 'Interactions').

4.9 Overdose

Symptoms: Hypermagnesaemia characterised by flushing, thirst, hypotension, drowsiness, nausea, vomiting, confusion, slurred speech, double vision, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, respiratory depression, electrolyte/fluid abnormalities (hypophosphatemia, hyperosmolar dehydration), ECG changes (prolonged PR, QRS and QT intervals), bradycardia, cardiac arrhythmias, coma and cardiac arrest.

Patients with renal failure and metabolic derangements develop toxicity at lower doses.

Treatment: Maintain respiration with 10% calcium gluconate administered intravenously in a dose of 10-20ml. If renal function is normal adequate fluids should be given to assist removal of magnesium from the body. Dialysis may be necessary in patients with renal impairment or severe hypermagnesaemia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Magnesium is the second most abundant cation in intracellular fluid and is an essential body electrolyte. Magnesium is a factor in a number of enzyme systems, and is involved in neurochemical transmission and muscular excitability.

Parenterally administered magnesium sulphate exerts a depressant effect on the central nervous system and acts peripherally to product vasodilation.

5.2 Pharmacokinetic properties

Following intravenous administration, the onset of action is immediate and the duration approximately 30 minutes. Following intramuscular administration the onset of action occurs after approximately one hour and the duration of action is 3-4 hours.

Magnesium sulphate is excreted by the kidneys with small amounts being excreted in breast milk and saliva.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide BP

Sulphuric acid BP

Water for injections HSE

6.2 Incompatibilities

Magnesium sulphate is incompatible with alkali hydroxides (forming insoluble magnesium hydroxide), alkali carbonates (forming insoluble magnesium carbonate) and salicylates. Streptomycin sulphate and tetramycin sulphate activity is inhibited by magnesium ions.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25^{o}C.

6.5 Nature and contents of container

Neutral Type I glass ampoules containing 2m1, 4m1 or 40m1, supplied in packs of 1, 5 or 10 units.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 35104/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/06/1987 / 18/11/2002

10 DATE OF REVISION OF THE TEXT

21/03/2014