SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Magnesium Sulfate 20%w/v Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Magnesium Sulfate heptahydrate 4g
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Sterile Solution for Injection
A clear, colourless solution practically free from visible particles

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of magnesium deficiency in hypomagnesaemia where the oral route of administration may be inappropriate.

To prevent further seizures associated with eclampsia.

4.2 Posology and method of administration

Posology

For intravenous administration (IV):

a) Treatment of magnesium deficiency in hypomagnesaemia:

Adults and the Elderly:
Dosage should be individualised according to patient's needs and responses.
Plasma magnesium levels should be monitored throughout therapy.

Up to 160 mmols of magnesium ions (200ml of a 20% solution) by slow intravenous infusion (in glucose 5%) over up to 5 days, may be required to replace the deficit (allowing for urinary losses). There are no data for the use by the IM route of the 20% solution.

Paediatric population:

Magnesium supplement in deficiency: 100mg/kg (0.5ml/kg of 20% solution or 0.4mmols/kg of magnesium ions) as a single dose, repeated every 12 hours as necessary.

Convulsions associated with low magnesium levels: 20-40mg/kg (0.1-0.2ml/kg of a 20% solution or 0.08-0.16 mmols/kg of magnesium ions) repeated every 4-6 hours as necessary.

There is very limited published data to suggest that an IM dosage should not exceed a concentration of 20%.

Renal Failure:
Doses must be reduced in renal failure. Caution must be observed to prevent exceeding the renal excretory capacity. The dosage should not exceed 20g in 48 hours (100ml of a 20% solution or 80mmols of magnesium ions).

b) To prevent further seizures associated with eclampsia*:*

Intravenous Maintenance Regimen

A loading dose of 4g/20ml or 16 mmols/20ml of magnesium ions IV (20ml of a 20% solution) or in some cases 5g/25ml or 20 mmols/25ml IV, as described above, is followed by an infusion of 1g/h continued for 24h after the last fit.

Recurrent Convulsions: In the IV regimen, if convulsions recur, a further 2-4g/10-20ml or 8-16 mmols/10-20ml of magnesium ions (depending on the woman's weight, 2g if less than 70Kg) is given IV over 5 min.

Appropriate reductions in dosage should be made for patients with renal impairment; a suggested dose reduction in severe renal impairment is a maximum of 20g (80 mmols of magnesium ions) over 48 hours.

Method of administration
Magnesium sulfate injection may be administered by intramuscular or intravenous routes.
Intramuscular therapy should be used only when peripheral venous access is impossible.
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4.3 Contraindications

Hypersensitivity to magnesium and its salts or to any of the excipients listed in section 6.1.
Magnesium sulfate is contraindicated in patients with severely impaired renal function.

4.4 Special warnings and precautions for use

Magnesium sulfate must be used with caution in patients suspected of or known to have renal impairment.

Magnesium sulfate 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 sulfate.

4.5 Interaction with other medicinal products and other forms of interaction

Administer with caution to patients receiving digitalis glycosides. Magnesium sulfate should not be administered concomitantly with high doses of barbiturates,opiods or hypnotics due to the risk of respiratory depression

The action of non-depolarising muscle relaxants such as tubocurarine is potentiated and prolonged by parenteral magnesium salts.

Concomitant use of calcium channel blockers such as nifedipine or nimodipine may 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 has not been established, however, in the medical emergency of a patient having Eclampsia, Magnesium Sulfate can be administered to relieve this condition, which may be life threatening to both mother and baby.
As with all drugs it is not advisable to administer magnesium sulfate 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

No studies on the effects on the ability to drive and use machines have been performed.

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 (hypophosphataemia, hyperosmolar dehydration), ECG changes (prolonged PR, QRS and QT intervals), bradycardia, cardiac arrhythmias, coma and cardiac arrest

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Appropriate action should be taken to reduce the blood level of magnesium to avoid hypermagnesaemia. Neuromuscular blockade associated with hypermagnesaemia may be reversed with calcium salts, such as Calcium Gluconate, which should be administered intravenously in a dose equivalent to 2.5 to 5mmol of calcium.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral Supplements,
ATC code: A12CC 02.

Magnesium is the second most abundant caution 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 sulfate exerts a depressant effect on the central nervous system and acts peripherally to produce 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 sulfate is excreted by the kidneys with small amounts being excreted in breast milk and saliva

5.3 Preclinical safety data

This product has been available for many years and its side effects and clinical profile are well-understood, therefore no further data is provided.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection
Hydrochloric Acid
Sodium Hydroxide

6.2 Incompatibilities

Streptomycin sulfate and tetramycin sulfate activity is inhibited by magnesium ions.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Protect from light.
Keep in outer carton.

6.5 Nature and contents of container

Neutral Type 1 glass ampoules 20ml, containing a 20% w/v sterile solution for injection of Magnesium Sulfate

6.6 Special precautions for disposal

Discard any unused solution at the end of the session in the appropriate manner. Do not use the product if the packaging is damaged.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL 12064 / 0048

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th January 1999

10 DATE OF REVISION OF THE TEXT

17/03/2017