1.3.1.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS **S3**

1 NAME OF THE MEDICINE

ADCO MAGNESIUM SULPHATE 50 % injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 mL ampoule contains magnesium sulphate heptahydrate 1 g (4 mmol/8 mEq/2 mL)

Sugar free

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Injection

A clear, colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hypomagnesaemia

4.2 Posology and method of administration

Posology

In the treatment of magnesium deficiency tetany, 2 to 4 mL of the 50 % solution every 4 hours is recommended.

Method of administration

It can be administered either intramuscularly or intravenously.

Intravenously 1 to 4 g may be given as a 10 or 20 % solution at a rate not exceeding 150 mg per minute. It may also be given by infusion. The blood pressure should be monitored during each injection.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Patients with impaired renal function (can produce toxic blood levels), severe renal impairment (glomerular filtration rate < 25 mL/h), renal failure, anuria
- Patients with intracranial pathology
- Children with intestinal parasitic diseases
- Hepatic encephalopathy, hepatic failure
- Patients with heart block (class I - III) or myocardial damage and myasthenia gravis

4.4 Special warnings and precautions for use

If administered intravenously, it must be given slowly.

ADCO MAGNESIUM SULPHATE 50 % should not be used in hepatic coma if there is a risk of renal failure.

Serum calcium levels and serum magnesium levels should be routinely monitored in patients receiving ADCO MAGNESIUM SULPHATE 50 %.

The absence of respiratory depression should be monitored: the breath rate should not be under 16 breaths/min.

The excretion of urine should not be under 25 mL/h, as it could lead to hypermagnesaemia.

The presence of the patellar reflex should be checked.

ADCO MAGNESIUM SULPHATE 50 % should be administered with caution if flushing and sweating occurs.

An antidote of injectable calcium gluconate solution should be immediately available.

ADCO MAGNESIUM SULPHATE 50 % should not be administered into muscles which are emaciated or atrophied. For intramuscular administration, the dorsogluteal muscle and sciatic nerve should be avoided.

If the total dose to be administered exceeds 5 mL, the injection volume should be divided between more than one deep muscular injection site.

Use caution in older or thin patients who may only tolerate up to 2 mL in a single injection. Do not use an injection site that has evidence of infection or injury. If repeating an intramuscular dose, rotate injection sites to avoid injury or discomfort to the muscles.

4.5 Interaction with other medicines and other forms of interaction

Muscle relaxants

The action of non-depolarising muscle relaxants is potentiated and prolonged by ADCO MAGNESIUM SULPHATE 50 %.

ADCO MAGNESIUM SULPHATE 50 % enhances non-depolarising muscle relaxant vecuronium action at adult muscle type nicotinic acetylcholine receptor.

Nifedipine

Profound hypotension may occur.

Calcium channel blockers or diuretics

There is a risk of cardiopulmonary events when intravenous ADCO MAGNESIUM SULPHATE 50 % is used concomitantly with calcium channel blockers or diuretics (such as thiazides and furosemide).

Calcium salts

Calcium salts may reduce the efficacy of ADCO MAGNESIUM SULPHATE 50 %. Several magnesium activated enzymes are inhibited by calcium.

Digitalis glycosides

ADCO MAGNESIUM SULPHATE 50 % should also be administered with caution to those patients receiving digitalis glycosides. Magnesium has been shown to block the transient inward current carried by calcium, which digitalis glucosides generate. However, ADCO MAGNESIUM SULPHATE 50 % given intravenously in adequate quantities (2 to 3 g in one minute followed by 2 g/h for 4 to 5 hours)

is effective in controlling ventricular irritability caused by toxic levels of digitalis preparations.

Neuromuscular blocking medicines

Parenteral administration of ADCO MAGNESIUM SULPHATE 50 % may enhance the effects of neuromuscular blocking medicines. The neuromuscular blocking effects of parenteral ADCO MAGNESIUM SULPHATE 50 % and aminoglycoside antibacterial medicines may be additive.

CNS depressants

When barbiturates, narcotics or other hypnotics (or systemic anaesthetics) are to be given in conjunction with ADCO MAGNESIUM SULPHATE 50 %, their dosage should be adjusted with caution because of additive depressant effects of ADCO MAGNESIUM SULPHATE 50 % and the risk of respiratory depression.

Medicine transporters

ADCO MAGNESIUM SULPHATE 50 % co-administration with cisplatin may reduce platina accumulation by regulating the expression of the renal transporters, rOct2 and rMate1 and, thereby, attenuate cisplatin (CDDP)-induced nephrotoxicity (CIN).

4.6 Fertility, pregnancy and lactation

Pregnancy

ADCO MAGNESIUM SULPHATE 50 % easily crosses the placenta, and foetal serum levels will closely mirror maternal estimations.

Sufficient amount of magnesium may cross the placenta in mothers treated with high doses, causing hypotonia and respiratory depression in newborns. When used in pregnant women, foetal heart rate should be monitored and use within 2 hours of delivery should be avoided.

ADCO MAGNESIUM SULPHATE 50 % can cause skeletal adverse effects when administered continuously for more than 5 to 7 days to pregnant women.
If prolonged or repeated exposure to ADCO MAGNESIUM SULPHATE 50 % occurs during pregnancy, monitoring of neonates for abnormal calcium or magnesium levels and skeletal adverse effects should be considered. Serum magnesium levels in preterm infants are higher than adult levels.

Breastfeeding

Safety during breastfeeding has not been established.

Fertility

No effects of ADCO MAGNESIUM SULPHATE 50 % on male and female fertility are anticipated.

4.7 Effects on ability to drive and use machines

ADCO MAGNESIUM SULPHATE 50 % is unlikely to affect the ability to drive or to operate machinery.
However, on the basis of the potential adverse effects, some people may feel dizzy or drowsy after receiving ADCO MAGNESIUM SULPHATE 50 %. Patients

should be advised not to drive or operate machinery, or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

a. Summary of the safety profile

Excessive administration of ADCO MAGNESIUM SULPHATE 50 % may lead to the development of symptoms of hypermagnesaemia which may include the adverse reactions listed in the table below.

b. Tabulated list of adverse reactions

System organ class	Frequency	Adverse reaction
Immune system disorders	Frequency unknown	Hypersensitivity reactions
Metabolism and nutrition disorders	Frequency unknown	Electrolyte/fluid abnormalities (hypophosphataemia, hypertonic dehydration) There have been isolated reports of maternal and foetal hypocalcaemia with high doses
Nervous system disorders	Frequency unknown	Respiratory depression,

		nausea, vomiting, drowsiness, confusion, coma, slurred speech, double vision, loss of tendon reflexes due to neuromuscular blockade
Cardiac disorders	Frequency unknown	Cardiac arrhythmias, cardiac arrest, ECG abnormal (prolonged PR, QRS and QT intervals), bradycardia
Vascular disorders	Frequency unknown	Flushing of the skin and hypotension due to peripheral vasodilatation
Musculoskeletal and connective tissue disorders	Frequency unknown	Muscle weakness
General disorders and administration site conditions	Frequency unknown	Thirst

c. Description of selected adverse reactions

Injection/infusion-related effects:

Too rapid administration: quickly developing vasodilatation, reduced blood pressure.

Local: irritant to veins, extravasation may cause tissue damage.

Intramuscular: pain, redness, swelling or warmth at the injection site, drainage at the injection site, prolonged bleeding, cellulitis, sterile abscess, signs of an allergic reaction, such as difficulty breathing or facial swelling, injury to nearby structures (blood vessels, bones, or nerves), inadvertent intravascular or intra-ostial injection, tissue necrosis, poor absorption due to high injection volume have been described for other magnesium sulfate solutions for injection.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website.

For reporting of side effects directly to the Holder of the Certificate of Registration, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

4.9 Overdose

Symptoms

Intravenous magnesium infusions can result in hypermagnesaemia even in the presence of normal kidney function. Clinical signs of overdose will be those of hypermagnesaemia.

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

Disappearance of the deep tendon reflex is a useful clinical sign to detect the onset of magnesium intoxication. Magnesium intoxication is manifested by a sharp drop in blood pressure and respiratory paralysis. The potential symptoms of hypermagnesaemia are as follows:

Magnesium levels			**Manifestation of overdose symptoms**
mg/dL	**mEq/L**	**mmol/L**	
< 1,2	< 1	< 0,5	Tetany, seizures, arrhythmias
1,2 – 1,8	1,0 – 1,5	0,5 – 0,75	Neuromuscular irritability, hypocalcaemia, hypokalaemia
1,8 – 2,5	1,5 – 2,1	0,75 – 1,05	Normal magnesium level
2,5 – 5,0	2,1 – 4,2	1,05 – 2,1	Typically asymptomatic
5,0 – 7,0	4,2 – 5,8	2,1 – 2,9	Lethargy, drowsiness, flushing, nausea and vomiting, diminished deep tendon reflex
7,0 – 12	5,8 – 10	2,9 – 5	Somnolence,

			loss of deep tendon reflexes, hypotension, ECG changes
> 12	> 10	> 5	Complete heart arrest, apnoea, paralysis, coma

Treatment:

In symptomatic hypermagnesaemia, administration of calcium, usually at a dose of 100 to 200 mg intravenously over 5 to 10 min, antagonises the toxic effects of magnesium.

In patients with severe renal dysfunction, peritoneal dialysis or haemodialysis will rapidly and effectively lower serum magnesium levels.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A.24 (Mineral Substitutes, Electrolytes)

Pharmacotherapeutic group: Electrolyte solutions, magnesium sulfate

ATC code: B05XA05

Magnesium is essential for the activity of many enzymes and plays a role in neurochemical transmission and muscular excitability.

5.2 Pharmacokinetic properties

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide (pH adjustment)

Sulphuric acid (pH adjustment)

Water for injection

6.2 Incompatibilities

DO NOT USE WITH: Sodium and potassium tartrates, soluble phosphates and arsenates, alkali carbonates and bicarbonates unless in a dilute solution. When used with certain bromides, concentrated solutions can give a precipitate.

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

ADCO MAGNESIUM SULPHATE 50 % is available in 2 mL single dose, semi-

rigid, transparent, low density polyethylene (LDPE) plastic ampoules.

Six strips of 10 ampoules are packed in an outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER(S)

V/24/253

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration: 15 September 1988

10. DATE OF REVISION OF THE TEXT

21 November 2025

Namibia: NS2 90/24/00217

Botswana: S2 B9315085