



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR,
PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr E van Zyl
Equity Pharmaceuticals (Pty) Ltd
100 Sovereign Road
Route 21 Corporate Park
Nellmapius Drive
Irene
Pretoria

Dear Mr van Zyl

Section 21 Extension Authorization for MAGNESIUM SULPHATE 50% INJECTION

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Magnesium Sulphate 50% Injection**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.

Section 21 Extension Authorisation re Magnesium Sulphate 50% INJ 16022026-1

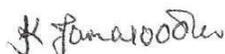
8. The full quantities imported in terms of this Section 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **13 August 2026**.

Table 1: Provincial usage data

Province	Six Months Estimate	Actual Uptake
Correctional Services	9	0
EC-MT	0	26 200
EC-PE	0	
FS	24 000	24 000
GP	108 000	0
KZN	79 500	79 500
LP	22 000	22 000
MP	24 900	0
NC	15 000	15 000
NW	25 800	25 800
SAMHS	1 500	0
WC	23 800	75 000
Total	324 509	267 500

Yours sincerely



KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT

DATE: 20/21/2026

Department of Health • Lefapha la Pholo • Lefapha la Bophelo • uMnyango wezeMpilo • Muhasho wa Mutakalo • Departement van Gesondheid • Kgoro ya Maphelo • Ndzawulo ya Rihanyo • LiTiko le Thempilo • ISebe lezeMpilo • UmNyango WezamaPhilo

Section 21 Outcome Letter

2026-02-13

Ms Buhle Mbongo

National Department Of Health

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):

Your application dated **2026-02-04** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**
- D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 7188**
- E. UNREGISTERED MEDICINES: GENERIC NAME: Mama**
- F. TRADE NAME: Magnesium Sulfate Injection USP 500 mg/mL**
- G. QUANTITY: 57504 Packs (1)**

H. LETTER NUMBER: S2100021520

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

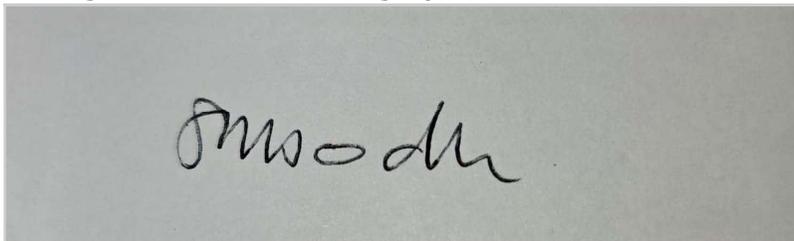
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'Ms Moropa' written in a cursive style.

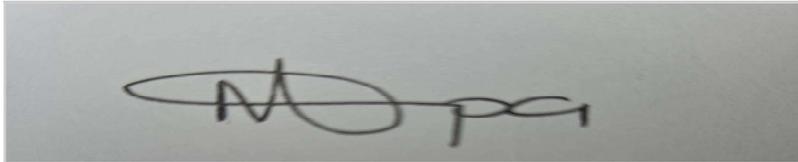
Ms Mahlodi Moropa

Final Approver

S2100021520



SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083





QUOTATION #20260204

TO: NATIONAL DEPARTMENT OF HEALTH

TEL: 012 395 9539

Email: section21quotes@health.gov.za

Contact person: Buhle Mbongo

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www.clinigengroup.com
www.equitypharma.co.za

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

PRODUCT CODE	DESCRIPTION	PACK SIZE	QUANTITY	PRICE EXCL	TOTAL INCL
MAG50K	Magnesium Sulfate Injection USP 1g/2ml	1 amps	1	R 2.64	R 3.04
			57 500	R 151 800.00	R 174 570.00
TOTAL:				R 151 800.00	R 174 570.00

This quote is valid for 180 days

Approval:


Ehrard van Zyl
Business Unit Manager -
Specialist Medicine

4 February 2026

Date

Approved by Ehrard van Zyl/ Carel Bouwer



Component : CARTON
Dimension : 150 x 17 x 75 mm
Colour : CMYK
Specification: Cyber XL 350 GSM
U.V (Double Coating) + 3D Hologram

1 g/2 ml
Magnesium Sulfate Injection USP

Magnesium Sulfate

Injection USP

1 g/2 ml
FOR IM OR IV USE

NOT FOR DIRECT INJECTION
MUST BE DILUTED BEFORE IV USE

10 ampoules of 2ml



Batch No. :
Mfg. Date :
Exp. Date :



Composition: Each ml contains:
Magnesium Sulfate
Heptahydrate USP 500 mg. eq. to
4.05 mOsmol /ml.
Water for Injection USP q.s.

Storage:
Store between temperature 20° to 25°C.
Protect from light.
Keep out of the reach of children.

Dosage: As directed by the Physician.

Mfg. Lic. No.: 1804-B
Manufactured by :
Kwality Pharmaceuticals Ltd.
Nag Kalan, Majitha Road, Amritsar- India

NOT FOR DIRECT INJECTION
MUST BE DILUTED BEFORE IV USE

1 g/2 ml
FOR IM OR IV USE

Magnesium Sulfate

Injection USP

Magnesium Sulfate

Injection USP

1 g/2 ml **FOR IM OR IV USE**

NOT FOR DIRECT INJECTION
MUST BE DILUTED BEFORE IV USE 10 ampoules of 2ml



Batch No. :
Mfg. Date :
Exp. Date :

1 g/2 ml
Magnesium Sulfate Injection USP

Leaflet Size 120 x 180mm

Magnesium Sulfate Injection USP

1 g/2 ml

COMPOSITION

Each ml contains:
Magnesium Sulfate Heptahydrate USP 500 mg
eq. to 4.05 mOsmol /ml.
Water for Injection USP q.s.

CATEGORY

Osmotic laxative; used in treatment of electrolyte deficiency.

PHARMACOLOGY

Magnesium is the second most plentiful cation of the intracellular fluids. It is essential for the activity of many enzyme systems and plays an important role with regard to neurochemical transmission and muscular excitability. Deficiencies are accompanied by a variety of structural and functional disturbances. Some of the effects of magnesium on the nervous system are similar to those of calcium. An increased concentration of magnesium in the extracellular fluid causes depression of the central nervous system (CNS). Magnesium has a direct depressant effect on skeletal muscle. Abnormally low concentrations of magnesium in the extracellular fluid result in increased acetylcholine release and increased muscle excitability that can produce tetany.

Magnesium slows the rate of SA nodal impulse formation. Higher concentrations of magnesium (greater than 15 mEq/L) produce cardiac arrest in diastole. Excess magnesium causes vasodilation by both a direct action on blood vessels and ganglionic blockade. Magnesium is excreted principally by the kidney by glomerular filtration.

PHARMACOKINETICS

Absorption : Immediately absorbed (IV) and last for approximately 30 minutes. Following IM administration, the onset of action occurs within 3 to 4 hours..

Distribution : Approximately 1% to 2% of total body magnesium is in the extracellular fluid space; 30% bound to albumin.

Metabolism : Magnesium is not metabolized.

Elimination : Excreted solely by the kidneys at a rate proportional to the serum concentration and glomerular filtration.

INDICATIONS AND USAGE

- As a CNS depressant, primarily in preeclampsia and eclampsia of pregnancy;
- As an electrolyte replenisher for hypomagnesemia and magnesium deficiency to maintain normal neuro muscular irritability.

DOSAGE AND ADMINISTRATION

Intravenous : 1 to 4 g Magnesium Sulfate Injection, USP 50% may be given intravenously in 10% to 20% solution, but only with great caution; the rate should not exceed 1.5 mL of 10% solution or equivalent per minute until relaxation is obtained.

Usual Dose Range : 1 to 40 g daily.

CONTRAINDICATIONS

Magnesium Sulfate Injection, USP 50% should not be administered parenterally in patients with heart block or myocardial damage.

SPECIAL PRECAUTIONS

Administer with caution if flushing and sweating occurs. When barbiturates, narcotics or other hypnotics (or systemic anesthetics) are to be given in conjunction with magnesium, their dosage should be adjusted with caution because of additive CNS depressant effects of magnesium. A preparation of calcium salt should be readily available for intravenous injection to counteract potential serious signs of magnesium intoxication. Since magnesium is excreted almost entirely by the kidneys, it should be given very cautiously in the presence of serious impairment of renal function.

DRUG INTERACTIONS

When barbiturates, narcotics, hypnotics (or systemic anesthetics), or other central nervous system depressants are to be given in conjunction with magnesium, their dosage should be adjusted with caution because of the additive central nervous system depressant effects of magnesium. Central nervous system depression and peripheral transmission defects produced by magnesium may be antagonized by calcium.

ADVERSE REACTIONS

Principal adverse reactions are related to the high plasma levels of magnesium and include flushing, sweating, hypotension, circulatory collapse, and cardiac and central nervous system depression. Respiratory depression is the most life-threatening effect.

STORAGE

Store between temperature 20° to 25°C. Protect from light.
Keep out of the reach of children.

PRESENTATION:

10 ampoules of 2 ml enclosed in a plastic tray and each tray packed in a printed carton.

Manufactured by :

Kwality Pharmaceuticals Ltd.

Nag Kalan, Majitha Road, Amritsar- India