1. Name of the medicinal Product

1.1 Name of the medicinal Product

Magnesium Sulphate Injection BP 50% W/V

1.2 Strength

Composition:

Magnesium Sulphate Heptahydrate BP 50% w/v

Water For Injections BP Q.S.

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

Magnesium Sulphate Heptahydrate BP

2.2 Quantitative Declaration

Sr. No.	Ingredients	Specifications	Label Claim (mg/ml)	Rational
1	Magnesium Sulphate Heptahydrate	BP	500	Anticonvulsant & Parenteral Magnesium Supplement
2	Charcoal Activated	BP	1.00	Adsorbent
3	Water For Injections	BP	Q.S.	Solvent

3. Pharmaceutical Form

Solution For Injection.

A clear colourless solution filled in glass ampoule.

4. Clinical Particulars

4.1 Therapeutic Indications

Convulsions associated with pre-eclampsia and eclampsia of pregnancy and to control convulsions associated with acute nephritis in children. Hypomagnesaemia especially acute cases accompanied by signs of tetany.

Magnesium Sulphate is indicated in uterine tetany and premature labour as a myometrial relaxant.

Arrhythmias

4.2 Posology and Method of Administration

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Usual Adult and Adolescent Dose:

Seizures in Toxaemia of Pregnancy:

IV. loading dose of 4 g is administered over up to 20 minutes, followed by either LV. infusion of 1 g l hour or deeply I.M. of 5 g into each buttock then 5 g I. M. on alternate buttocks every 4 hours as needed.

Premature Labour:

Initially: 4- 6 g by LV infusion (in 250 ml of Dextrose 5% or 0.9% Sodium chloride) over 20-30 minutes.

Maintenance Dose: I. V. infusion of I - 3 g 1 hour until contractions abate.

Hypomagnesaemia:

Mild deficiency:

I.M.: 1 g administered every 6 hours.

Severe deficiency:

I.M.: 250 mg/kg body weight within a four hour period or by:

I.V. Infusion:

5 gm in 1 liter of 5% Dextrose or 0.9% Sodium chloride solutions administered slowly over a three hour period.

The Maximum Adult dose is 40 g/day.

Paediatric Dose:

Anticonvulsant:

I.M.: 1 0 - 40 mg/kg as needed to control convulsions.

4.3 Contraindications

Magnesium sulphate should not be administered parenterally in patients with heart block or myocardial damage. LV. magnesium should not be given to mothers with toxemia of pregnancy during the 2 hours preceding delivery.

4.4 Special Warnings and Special Precautions for Use

Warning:

IV use in eclampsia is reserves for immediate control of life threatening convulsion.

Magnesium sulfate should be given very cautiously in the presence of serious impairment of renal function since it is excreted almost entirely by the kidneys. This drug is excreted into breast milk.

Consult your doctor before breast-feeding.

Precautions:

Monitor serum magnesium levels and clinical status to avoid overdosage.

Maintain urine output at level of 100 ml every 4 hours.

4.5 Interaction wih other medicinal products and other forms of interaction

Concurrent use with calcium salts may neutralize effects of Magnesium Sulphate. Parenteral Magnesium Sulphate in digitalized patients may cause cardiac conduction defects.

Magnesium Sulphate potentiates the action of neuromuscular blockade. Magnesium Sulphate may potentiate the action of C.N.S. depressants.

4.6 Fertility, Pregnancy and Lactation

Lactation: This drug is excreted into breast milk. Consult your doctor before breast-feeding.

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

Flushing, sweating, hypotension, depressed reflexes, flaccid paralysis, hypothem1ia, circulatory collapse, cardiac and CNS depression proceeding to respiratory paralysis.

Hypocalcaemia with sign of tetany secondary to magnesium sulfate therapy for eclampsia has occurred..

4.9 Overdose

Sharp drop in blood pressure and respiratory paralysis. ECG changes reported include increased PR interval, increase QRS complex and prolonged QT interval . Heart block and a systole may occur.

Provide artificial ventilation until a calcium salt can be injected I.V. to antagonize the effects of magnesium. A dose of 5 to 10 m E.q. calcium will usually reverse respiratory depression and heart block.

Peritoneal dialysis or hemodialysis is also effective.

Hypem1agnesemia in the new born may require resuscitation and assisted ventilation via endotracheal intubation or intermittent positive pressure ventilation as well as intravenous calcium.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

Anticonvulsant & Parenteral magnesium supplement.

Magnesium prevents or controls convulsions by blocking neuromuscular transmission and decreasing the amount of acetylcholine liberated at the end plate by motor nerve impulse. Magnesium has a CNS depressant effect

5.2 Pharmacokinetic Properties

With I.V use, the onset of anticonvulsant action is immediate and lasts about 30 minutes. With IM use, on set occurs in 1 hour and persists for 3 to 4 hours. Effective anticonvulsant serum levels range from 2.5 or 3to 7.5 m.Eq /L. Magnesium is excreted by the kidney.

5.3 Preclinical Safety Data

Not Applicable

6 Pharmaceutical Particulars

6.1 List of Excipients

Charcoal Activated BP

Water For Injections BP

6.2 Incompatibilities

None.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store at controlled room temperature !5° -30° C. Avoid freezing.

6.5 Nature and Contents of Container

A clear colourless solution filled in 10 ml glass ampoule. Such 5 ampoules are tray packed in printed baby carton with packing insert. Such 10 baby cartons are packed in Printed carton.

6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

7.1 Name and Address of Marketing Authorization Holder

ZOLON HEALTHCARE E LTD.

37 OSOLO WAY, AJAO ESTATE,

ISOLO, LAGOS,

NIGERIA.

E-mail: info@zolonhealthcare.com

7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited

Trimul Estate, Khatraj, Taluka: Kalol,

District: Gandhinagar Gujarat, India.

Telephone no.: +91-02764-665000

Fax: +91-02764-281809

Email: info@lincolnpharma.com

Website: www.lincolnpharma.com

7.3 Marketing Authorization Number

To be included after obtaining first registration.

7.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

8. Date of Revision of the Text

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9. Dosimetry (If Applicable)

Not Applicable

10. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable