

# Nalepsin®

(Magnesium Sulphate heptahydrate 4.0% w/v)

Intravenous Infusion BP

## Presentation

Nalepsin is a sterile intravenous infusion and ready-to-use, pyrogen free, isotonic solution of Magnesium Sulphate Heptahydrate. Each 100ml intravenous solution contains 16.4 mmol of magnesium as magnesium sulphate heptahydrate BP4.0g

## Description

Magnesium is the second most plentiful cation of intracellular fluid and is involved in a wide range of activities. It is needed for activity of many enzymes and plays a role in neurochemical transmission and muscular excitability. Abnormally low concentration of magnesium in the ECF results in increased acetylcholine release and increased muscle excitability that can produce tetany. Magnesium Sulphate heptahydrate has anticonvulsant properties when administered parenterally. An increased concentration of magnesium in the ECF causes depression of the central nervous system (CNS). Magnesium has a direct effect on skeletal muscle. Hypomagnesaemia may develop from diarrhoea, stoma or fistula, alcoholism or diuretic therapy, prolonged treatment with aminoglycosides, hypocalcaemia, hypokalaemia and hyponatraemia.

After administration 25-30% of magnesium is protein bound. It is excreted mainly in the urine, over 90% of magnesium filtered by the kidney is reabsorbed. Small amounts are excreted in the faeces, breast milk and saliva. Magnesium also crosses the placenta.

## Indications

Nalepsin is indicated in the following conditions:

1. To prevent convulsion in patients with preeclampsia, eclampsia, tetanus and acute uraemia.
2. In acute myocardial infarction, arrhythmia.
3. To arrest premature labour.
4. As an adjuvant in neurosurgery to lower the C.S.F pressure.
5. For replacement therapy in hypomagnesaemia
6. To control hypertension, encephalopathy and convulsion associated with acute nephritis in children.

## Dosage and Administration

Usual dose range: Upto 40 g daily at a rate not exceeding 3 ml per minute  
*Seizure prophylaxis in Preeclampsia and Eclampsia* : A loading dose of 4g (100 ml) over upto 20 minutes followed by a maintenance dose of 2g (50ml) per hour. Recurrence of seizure may require an additional I.V bolus of 8-16 mmol ( upto 100ml ). For seizure prophylaxis, treatment should continue during labour and for atleast 24 hours after delivery.  
*In Myocardial infarction* : 8 mmol (50ml) over 20 minutes, then 65 mmol (400ml) over 24 hours. *In Magnesium deficiency* : 0.5-1 mmol / kg/day (200ml to 400ml) on the first day followed by 25 mmol (150ml) daily, upto 160 mmol (1000ml) over upto 5 days. *In Tetanus* : An infusion of Magnesium Sulphate sufficient to maintain a blood magnesium concentration of 2.5 to 4 mmol per litre has been recommended. *In arrhythmia* : 8 mmol (50 ml) over 10-15 minutes (repeated once if needed)

## Adverse Effects

Excessive administration of magnesium results in hypermagnesaemia manifested by nausea, vomiting, flushing of the skin, thirst, hypotension, drowsiness, confusion, loss of

tendon reflexes, respiratory depression, cardiac arrest etc.

## Drug Interactions

Concomitant use of magnesium salts with barbiturates, narcotics, hypnotics or other C.N.S depressants need dose adjustment because of additive effect on C.N.S.

## Precautions

Magnesium salts should be used with caution in patients with impaired renal and hepatic function.

## Contraindications

It is contraindicated in patients with heart block or myocardial damage.

## In Pregnancy and Lactation

Magnesium Sulphate crosses the placenta. So, as with any other drugs, caution is required when the drug is administered to pregnant women.

It is not known whether the drug is excreted in human milk. As it happens with many other drugs, cautions should be taken when it is administered to a nursing mother.

## Treatment of overdose

Magnesium Sulphate overdose can be treated with 10ml of 10% calcium gluconate or chloride intravenously. If the renal function is normal, adequate fluid should be given. Dialysis may be performed in renal impairment.

## Warning

Infusion of fluid should be immediately discontinued if rigor arises from any reason during the process. Do not use if the bottle is leaking, solution is cloudy, contains particles or after expiry date.

## Pharmaceutical Precautions

Store at controlled room temperature. Protect from light. This IV infusion is not intended for multi-dose use.

## Packaging

Nalepsin is available in 100ml polyethylene bottle containing Magnesium Sulphate heptahydrate BP4.0% w/v.



Manufactured by

**BEXIMCO PHARMACEUTICALS LTD.**

TONGI, BANGLADESH

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