WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Magnesium sulfate-Kalceks 500 mg/ml solution for injection, BP*

International Nonproprietary Name (INN)/strength/pharmaceutical form:
Magnesium Sulfate 500 mg/ml Solution for Injection (2 ml)

Abstract

Magnesium sulfate-Kalceks 500 mg/ml solution for injection, BP manufactured at HBM Pharma s.r.o., Martin, Slovakia was included in the WHO list of prequalified medicinal products for treatment of reproductive health indications in women on 04 July 2017.

Magnesium sulfate-Kalceks is indicated for:

- treatment of women with eclampsia
- prevention of eclampsia in women with severe pre-eclampsia
- prevention of cerebral palsy in the infant in women at risk of imminent preterm birth before 32 weeks of gestation.

Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredient (API) of Magnesium sulfate-Kalceks is magnesium sulfate heptahydrate.

The most serious safety concerns observed during treatment with magnesium sulfate heptahydrate are hypersensitivity reactions, hypocalcemia, pain with intramuscular injection and hypermagnesemia 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 (hypophosphatemia, hyperosmolar dehydration), ECG changes (prolonged PR, QRS and QT intervals), bradycardia, cardiac arrhythmias, coma and cardiac arrest.

The efficacy and safety profile of Magnesium sulfate-Kalceks is well established based on extensive clinical experience in women for the indicated conditions.

On the basis of data submitted and public information on the use of magnesium sulfate heptahydrate for reproductive health indications in women, the team of assessors advised that Magnesium sulfate-Kalceks is of acceptable quality, efficacy and safety to allow inclusion of Magnesium sulfate-Kalceks in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the Proprietary Name is given as an example only.

Summary of Prequalification Status for Magnesium sulfate-Kalceks:

	Initial Acceptance					
	Date	**Outcome**	**Date**	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	04 July 2017					
Dossier Evaluation (Quality assurance)						
Quality	26 June 2017	MR				
Bioequivalence	29 June 2017	MR				
Inspection Status						
GMP(re-)inspection						
API	NA	NA				
FPP	NA	NA				
GCP/GLP (re-)inspection	NA	NA				

MR: meets requirements
NA: not applicable, not available