WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Magnesium Sulfate 50% w/v Solution for Injection [1]

International Nonproprietary Name (INN):
Magnesium Sulfate Heptahydrate 50% Solution for Injection **(2 ml)**

Abstract

Magnesium sulfate 50% w/v Solution for Injection (2 ml) manufactured at Aurum Pharmaceuticals Ltd United Kingdom was submitted to be considered for prequalification in 2017 when the product was licensed / registered in the United Kingdom and subsequently accepted for the WHO list of prequalified products for the treatment of reproductive health conditions in women on 12 Dec 2017.

The "Procedure for prequalification of pharmaceutical products[2]" defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme (PQP) is based on the approval by a stringent regulatory authority (SRA), namely the United Kingdom "Medicines & Healthcare products Regulatory Agency" (MHRA, https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities" [3].

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme. However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant.
Based on the submitted stability data WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

"Do not store above 30°C.
The shelf-life at this storage condition is 36 months."

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken

[1] 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.
[2] http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS961_Annex10.pdf
[3] http://apps.who.int/prequal/info_general/documents/TRS986/TRS986_ANNEX-5_SRA-Guide.pdf https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

after prequalification (http://www.mhra.gov.uk/spc-pil/index.htm?secLevelIndexChar=Ma - Md#retainDisplay)

Parts 2a, 2b, 5 and 7 of the WHOPAR for Magnesium Sulfate 50% w/v Solution for Injection are included here.

Magnesium Sulfate 50% w/v Solution for Injection contains magnesium sulfate heptahydrate. Its WHO recommended use is 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.

The most frequent adverse reactions of magnesium sulfate heptahydrate are pain with intramuscular injection and hypomagnesemia. Symptoms include 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 most serious adverse reactions of magnesium sulfate heptahydrate are hypersensitivity reactions and hypocalcaemia.

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

Summary of Prequalification Status for
Magnesium Sulfate 50% w/v Solution for Injection

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	12 Dec 2017	listed		
Dossier Evaluation	30 Nov 2017	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.