WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Magnesiumsulfat 50% Inresa[1]

International Nonproprietary Name (INN):
Magnesium sulfate heptahydrate 500 mg/ml Injection

Abstract

Magnesiumsulfat 50% Inresa, manufactured at Inresa Arzneimittel GmbH was submitted to be considered for prequalification in 2016 when the product was licensed / registered in Germany and subsequently accepted for the WHO list of prequalified products for (pre-) eclampsia (pregnancy related disorders) on 15 August 2016.

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 German "Federal Institute for Drugs and Medical Devices" (www.bfarm.de), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"[3] [4].

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.
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 25°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 after the prequalification (https://www.pharmnet-bund.de/dynamic/de/arzneimittel-informationssystem/index.html) Application No. 6914444.00.00, last accessed February 2017).

[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://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS986annex5.pdf?ua=1
[4] https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_Sept2016.pdf

The English language version of the Patient Information Leaflet, the Summary of Product Characteristics and the labelling, which is a company authorized English translation of the approved German texts, are included in this WHOPAR.

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for Magnesiumsulfat 50% Inresa are included here.

Magnesiumsulfat 50% Inresa contains magnesium sulfate. Its recommended use is for the treatment of pre-eclampsia and eclampsia in women.

The most frequent adverse events observed during treatment with magnesium sulfate were flushing, nausea or vomiting, headache, muscle weakness, absent or reduced tendon reflexes, The most serious adverse effects of magnesium sulfate are hypotension, heart palpitations, tachycardia and respiratory depression.

The efficacy and safety profile of Magnesiumsulfat 50% Inresa is well established based on the extensive clinical experience in the management of (pre-) eclampsia.

Summary of Prequalification Status for Magnesiumsulfat 50% Inresa

	Initial Acceptance			
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list, i.e. date of listing	15 August 2016	listed		
Dossier Evaluation	12 July 2016	MR		

MR: meets requirements

The table represents the status of relevant completed activities only.