WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Magnesium sulfate 50% Inresa[1]

Magnesium sulfate 50% w/v solution for injection, 10 mL

Magnesium sulfate 50% Inresa was submitted in 2016 by Inresa Arzneimittel GmbH to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for treatment of reproductive health conditions in women on 15 August 2016.

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information https://extranet.who.int/prequal/medicines/rh062

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 Team: Medicines (PQTm), is based on the approval by 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].

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 in hot and very humid areas, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[4].

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:

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aae767d_2

[4] https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

- Do not store above 30°C.
- The shelf-life at this storage condition is 60 months

This WHOPAR refers to the information available at the approving stringent regulatory authority's website resulting from the assessment of the quality, efficacy and safety as well as steps taken after approval:

https://portal.dimdi.de/amguifree/termsofuse.xhtml

https://portal.dimdi.de/amguifree/am/docoutput/jpadocdisplay.xhtml?globalDocId=375A10323B104E51B8ED4707DFF8F46F&directdisplay=true&docid=1

Application No. 6914444.00.00

For details on the uses of this product, for relevant efficacy and safety information see the summary of product characteristics and the patient information leaflet.

The English language version of the patient information leaflet, the summary of product characteristics and the labelling, as certified to be "BfArM" approved texts, are included in this WHOPAR.

This WHOPAR for Magnesium sulfate 50% Inresa is comprised of parts 2, 3. 4. 5 and 7.

Magnesium sulfate 50% Inresa contains magnesium sulfate heptahydrate.

Its WHO recommended use is for therapeutic treatment of pre-eclampsia and eclampsia in women.

Summary of Prequalification Status for Magnesium sulfate 50% Inresa

	Initial Acceptance		**Requalification**	
	Date	**Outcome**	**Date**	**Outcome**
Status on PQ list	15 August 2016	listed	30 October 2024	listed
Dossier Evaluation	July 2016	MR	October 2024	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.