

## **WHO Prequalification Programme WHO PUBLIC ASSESSMENT REPORT (WHOPAR)**

### **Sulfato de Magnésio Labesfal Solução Injectável 5000 mg/10 ml Solução injectável<sup>1</sup> (Magnesium Sulphate Labesfal 5000 mg/10 ml solution for injection)**

Magnesium sulfate 500 mg/mL (10 mL) solution for injection

Magnesium Sulphate Labesfal 5000 mg/10 ml solution for injection was submitted in 2018 by Labesfal - Laboratórios Almiro S.A. Portugal to be considered for prequalification and subsequently accepted for the WHO list of prequalified products for the treatment of reproductive health conditions in women on 19 June 2018.

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/rh072>

The “Procedure for prequalification of pharmaceutical products<sup>2</sup>” 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 Portuguese INFARMED - National Authority of Medicines and Health Products, IP (<http://www.infarmed.pt/>) in line with the “Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities”<sup>3</sup>.

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<sup>4</sup>.

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 60 months.

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<sup>1</sup> 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.

<sup>2</sup> [https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47\\_2](https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2)

<sup>3</sup> [https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aac767d\\_2](https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs986-annex5.pdf?sfvrsn=8aac767d_2)

<sup>4</sup> [https://extranet.who.int/prequal/sites/default/files/document\\_files/48%20Stability%20data%20SRA%20FPPs\\_March2016\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf)

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://extranet.infarmed.pt/INFOMED-fo/pesquisa-avancada.xhtml> registration number: 3259595)

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 "INFARMED" approved texts, are included in this WHOPAR.

This WHOPAR for Magnesium Sulphate Labesfal is comprised of parts 2, 3, 4, 5 and 7.

Magnesium Sulphate Labesfal contains magnesium sulphate 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

**Summary of Prequalification Status for  
Magnesium Sulphate Labesfal 5000 mg/10 ml solution for injection**

	Initial Acceptance		Requalification	
	Date	Outcome	Date	Outcome
Status on PQ list	19 June 2018	listed	26 January 2026	listed
Dossier Evaluation	May 2018	MR	January 2026	requalified
PQ: prequalification MR: meets requirements				

The table represents the status of relevant completed activities only.