WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Sulfato de Magnésio Labesfal Solução Injectável 5000 mg/10 ml Solução injectável[1]

International Nonproprietary Name (INN):
Magnesium sulfate heptahydrate 500 mg/mL Solution for Injection (10 ml)

Abstract

Sulfato de Magnésio (Labesfal Solução Injectável 5000 mg/10 ml Solução injectável), manufactured at Labesfal, Laboratórios Almiro S.A. 3465-157 Santiago de Besteiros Portugal was submitted to be considered for prequalification in 2018 when the product was licensed / registered in the Portugal and subsequently accepted for the WHO list of prequalified products for the treatment of reproductive health conditions in women on 19 June 2018.

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 Portuguese "Infarmed" (http://www.infarmed.pt/) 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 60 months."

[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

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 Portuguese texts, are included in this WHOPAR.

Parts 2a, 2b, 3, 4, 5 and 7 of the WHOPAR for Sulfato de Magnésio are included here.

Sulfato de Magnésio 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 Sulfato de Magnésio

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list	19 June 2018	listed
Dossier Evaluation	25 May 2018	MR

MR: meets requirements