WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[RH086 trade name]*

Magnesium Sulfate Heptahydrate 500 mg/mL Solution for Injection

[RH086 trade name] manufactured at Joint Stock Company "Halychpharm" Lviv, Ukraine was included in the WHO list of prequalified medicinal products for treatment of reproductive health conditions in women on 16 March 2020.

[RH086 trade name] is indicated for the prevention of eclampsia in women with severe pre-eclampsia, treatment of women with eclampsia and prevention of cerebral palsy in the infant of women at risk of imminent preterm birth before 32 weeks of gestation. Detailed information on the use of this product is described in the summary of product characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients of [RH086 trade name] Magnesium suphate heptahydrate.

The efficacy and safety profile of Magnesium sulphate are well established based on extensive clinical experience in women for the indicated conditions. For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of [RH086 trade name] for treatment of reproductive health conditions in women, the team of assessors advised that [RH086 trade name] is of acceptable quality, efficacy and safety to allow inclusion of RH086 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [RH086 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 March 2020	listed
Quality	28 Feb 2020	MR
Bioequivalence	10 March 2020	MR
Safety, Efficacy	NA	NA
GMP (re-)inspection		
API	NA	NA
FPP	18 Dec 2018	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.