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This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Magnesium sulfate hydrate (preparations indicated for eclampsia)

March 30, 2021

Therapeutic category

Purgatives and clysters

Non-proprietary name

Magnesium sulfate hydrate

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

Current	Revision
(N/A)	Important Precautions
	Increased risks of hyperkalaemia have been reported in preterm
	infants born to mothers who were co-administered magnesium
	sulfate hydrate (injection) with ritodrine hydrochloride (injection).
	ECG or monitoring of serum potassium levels should be properly
	performed in such neonates regardless of the presence of
	symptoms if mothers received this drug for eclampsia during
	administration of ritodrine hydrochloride (injection), and
	appropriate measures should be taken if any abnormalities are
	observed.
Drug Interactions	Drug Interactions
Precautions for Co-administration	Precautions for Co-administration
(N/A)	Drugs Signs, Symptoms, Mechanism and
	and Treatment Risk Factors
	Ritodrine Increased risks of Mechanism
	<u>hydrochloride</u> <u>hyperkalaemia have</u> <u>unknown</u>
	(injection) been reported in
	infants born preterm.

N/A: Not Applicable. No corresponding language is included in the current package insert.

[Reference] Yada, Y., et al.: Scientific Reports 2020;10(1):7804