

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



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/glucose (preparations indicated for inhibition of uterine contractions in threatened premature labour, and prophylaxis and treatment of eclampsia in severe hypertensive disorders of pregnancy)

July 20, 2021

Therapeutic category

Other agents for uro-genital and anal organ

Non-proprietary name

Magnesium sulfate hydrate/glucose

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>(N/A)</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p><u>With prolonged administration of this drug during pregnancy, rickets-like bone lesion may be identified in neonates at birth.</u></p> <p><u>(The shortest duration of administration with magnesium sulfate hydrate/glucose (injections) to the mother was 18 days as confirmed among the cases reported after the product launch in Japan.)</u></p>

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

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