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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 prophylaxis and treatment of eclampsia in severe hypertensive disorders of pregnancy)

July 20, 2021

Therapeutic category

Antispasmodics

Non-proprietary name

Magnesium sulfate hydrate/glucose

Safety measure

Precautions should be revised in the package insert.

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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
Use during Pregnancy, Delivery or Lactation (N/A)	Use during Pregnancy, Delivery or Lactation <u>With prolonged administration of this drug during pregnancy, rickets-like bone lesion may be identified in neonates at birth. (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>

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

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