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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)

July 20, 2021

### **Therapeutic category**

Purgatives and clysters

### **Non-proprietary name**

Magnesium sulfate hydrate

### **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
<p>Use during Pregnancy, Delivery or Lactation</p> <p><u>With administration of this drug for eclampsia, hypokinesia in foetuses as well as heart failure, hyperkalaemia, or hypocalcaemia in neonates may occur.</u></p>	<p>Use during Pregnancy, Delivery or Lactation</p> <p><u>When administering this drug for eclampsia, caution should be exercised for the following:</u></p> <ul style="list-style-type: none"> <li>• <u>With administration of this drug during pregnancy, hypokinesia in foetuses as well as heart failure, hyperkalaemia, or hypocalcaemia in neonates may occur.</u></li> <li>• <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></li> </ul>

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>&lt;Eclampsia&gt;</p> <p><u>With administration of this drug for eclampsia, hypokinesia in</u></p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>&lt;Eclampsia&gt;</p> <p><u>With administration of this drug during pregnancy, hypokinesia in</u></p>

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foetuses as well as heart failure, hyperkalaemia, or hypocalcaemia in neonates may occur.

(N/A)

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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.)

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

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