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

March 30, 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.

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>Important Precautions (N/A)</p> <p>Drug Interactions Precautions for Co-administration (N/A)</p>	<p>Important Precautions <u>Increased risks of hyperkalaemia have been reported in preterm infants born to mothers who were co-administered this drug 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 these drugs were co-administered to mothers, and appropriate measures should be taken if any abnormalities are observed.</u></p> <p>Drug Interactions Precautions for Co-administration</p> <table border="1" data-bbox="1133 906 1960 1246"> <thead> <tr> <th data-bbox="1133 906 1406 1002">Drugs</th> <th data-bbox="1406 906 1680 1002">Signs, Symptoms, and Treatment</th> <th data-bbox="1680 906 1960 1002">Mechanism and Risk Factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1133 1002 1406 1246"><u>Ritodrine hydrochloride (injection)</u></td> <td data-bbox="1406 1002 1680 1246"><u>Increased risks of hyperkalaemia have been reported in infants born preterm.</u></td> <td data-bbox="1680 1002 1960 1246"><u>Mechanism unknown</u></td> </tr> </tbody> </table>	Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	<u>Ritodrine hydrochloride (injection)</u>	<u>Increased risks of hyperkalaemia have been reported in infants born preterm.</u>	<u>Mechanism unknown</u>
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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

Note: Designated as a drug requiring preparation of a Drug Guide for Patients

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>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p>(N/A)</p> <p>10. INTERACTIONS</p> <p>10.2 Precautions for Co-administration</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><Common to all indications></p> <p><u>Increased risks of hyperkalaemia have been reported in preterm infants born to mothers who were co-administered this drug 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 these drugs were co-administered to mothers, and appropriate measures should be taken if any abnormalities are observed.</u></p> <p>10. INTERACTIONS</p> <p>10.2 Precautions for Co-administration</p> <table border="1" data-bbox="1144 1098 1960 1340"> <thead> <tr> <th data-bbox="1144 1098 1413 1198">Drugs</th> <th data-bbox="1413 1098 1682 1198">Signs, Symptoms, and Treatment</th> <th data-bbox="1682 1098 1960 1198">Mechanism and Risk Factors</th> </tr> </thead> <tbody> <tr> <td data-bbox="1144 1198 1413 1340"><u>Uterine contraction inhibitors</u> <u>Ritodrine</u></td> <td data-bbox="1413 1198 1682 1340"><u>Increased risks of hyperkalaemia have been reported in</u></td> <td data-bbox="1682 1198 1960 1340"><u>Mechanism unknown</u></td> </tr> </tbody> </table>			Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors	<u>Uterine contraction inhibitors</u> <u>Ritodrine</u>	<u>Increased risks of hyperkalaemia have been reported in</u>	<u>Mechanism unknown</u>
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