Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Ritodrine hydrochloride (injections)

March 30, 2021

Therapeutic category

Other agents for uro-genital and anal organ

Non-proprietary name

Ritodrine hydrochloride

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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.

<table>
<tr><th>Current</th><th>Revision</th></tr>
<tr><td>Important Precautions
(N/A)</td><td>Important Precautions
<u>Increased risks of hypoglycaemia have been reported in preterm infants born to mothers who were administered this drug. Blood sugar levels in such neonates should be properly monitored regardless of the presence of symptoms, and appropriate measures should be taken if any abnormalities are observed.</u>

<u>Increased risks of hyperkalaemia have been reported in preterm infants born to mothers who were co-administered this drug with magnesium sulfate hydrate (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></td></tr>
<tr><td>Drug Interactions
Precautions for Co-administration
(N/A)</td><td>Drug Interactions
Precautions for Co-administration
<table><tr><th>Drugs</th><th>Signs, Symptoms, and Treatment</th><th>Mechanism and Risk Factors</th></tr><tr><td><u>Magnesium sulfate hydrate (injection)</u></td><td><u>Increased risks of hyperkalaemia</u></td><td><u>Mechanism unknown</u></td></tr></table></td></tr>
</table>

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

	have been reported in infants born preterm.
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions Neonatal hyperkalaemia: Hyperkalaemia may occur in neonates. Careful monitoring should be performed, and appropriate measures should be taken if any abnormalities are observed.

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.

<table>
<tr><th>Current</th><th>Revision</th></tr>
<tr><td>8. IMPORTANT PRECAUTIONS
(N/A)

(N/A)

10. INTERACTIONS
10.2 Precautions for Co-administration
<table><tr><th>Drugs</th><th>Signs, Symptoms, and Treatment</th><th>Mechanism and Risk Factors</th></tr><tr><td>Magnesium sulfate hydrate (injection)</td><td>Increased CK, respiratory depression,</td><td>Mechanism unknown</td></tr></table></td><td>8. IMPORTANT PRECAUTIONS
<u>Increased risks of hypoglycaemia have been reported in preterm infants born to mothers who were administered this drug. Blood sugar levels in such neonates should be properly monitored regardless of the presence of symptoms, and appropriate measures should be taken if any abnormalities are observed.</u>

<u>Increased risks of hyperkalaemia have been reported in preterm infants born to mothers who were co-administered this drug with magnesium sulfate hydrate (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>

10. INTERACTIONS
10.2 Precautions for Co-administration
<table><tr><th>Drugs</th><th>Signs, Symptoms, and Treatment</th><th>Mechanism and Risk Factors</th></tr><tr><td>Magnesium sulfate hydrate (injection)</td><td>Increased CK, respiratory depression,</td><td>Mechanism unknown</td></tr></table></td></tr>
</table>

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

	or cardiovascular adverse reactions (chest pain, myocardial ischaemia) may occur.	

11. ADVERSE REACTIONS

11.1 Clinically Significant Adverse Reactions

(N/A)

	or cardiovascular adverse reactions (chest pain, myocardial ischaemia) may occur. Increased risks of hyperkalaemia have also been reported in infants born preterm.	

11. ADVERSE REACTIONS

11.1 Clinically Significant Adverse Reactions

Neonatal hyperkalaemia

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