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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

Ritodrine hydrochloride (oral dosage form)

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

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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>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Occurrence of pulmonary oedema, heart failure, agranulocytosis, decreased white blood cell, thrombocytopenia, shock, arrhythmia, hepatic impairment, jaundice, toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson Syndrome), pleural effusion, intestinal obstruction in mothers, heart failure in foetuses and neonates, hypertrophy of the interventricular septum wall in neonates, and neonatal hypoglycaemia have been reported with ritodrine injections. Careful monitoring should be performed and appropriate measures should be taken if any abnormalities are observed.</p>	<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Occurrence of pulmonary oedema, heart failure, agranulocytosis, decreased white blood cell, thrombocytopenia, shock, arrhythmia, hepatic impairment, jaundice, toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson Syndrome), pleural effusion, intestinal obstruction in mothers, heart failure in foetuses and neonates, hypertrophy of the interventricular septum wall in neonates, neonatal hypoglycaemia, <u>and neonatal hyperkalaemia</u> have been reported with ritodrine injections. Careful monitoring should be performed and appropriate measures should be taken if any abnormalities are observed.</p>

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

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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>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>Occurrence of pulmonary oedema, heart failure, agranulocytosis, decreased white blood cell, thrombocytopenia, shock, arrhythmia, hepatic impairment, jaundice, toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson Syndrome), pleural effusion, intestinal obstruction in mothers, heart failure in foetuses and neonates, reversible hypertrophy of the interventricular septum wall in neonates, and neonatal hypoglycaemia have been reported with ritodrine injections.</p>	<p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>Occurrence of pulmonary oedema, heart failure, agranulocytosis, decreased white blood cell, thrombocytopenia, shock, arrhythmia, hepatic impairment, jaundice, toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson Syndrome), pleural effusion, intestinal obstruction in mothers, heart failure in foetuses and neonates, reversible hypertrophy of the interventricular septum wall in neonates, <u>neonatal hypoglycaemia, and neonatal hyperkalaemia</u> have been reported with ritodrine injections.</p>

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