

Published by
Ministry of Health, Labour and Welfare



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

Diazoxide

October 12, 2023

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Diazoxide

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.7 Pediatric Use</p> <p>Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken. Pulmonary hypertension may occur.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Serious fluid retention, congestive heart failure</p> <p>Serious sodium retention, fluid retention <u>and</u> congestive heart failure may occur. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures, such as administration of diuretics, should be taken.</p> <p>(N/A)</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.7 Pediatric Use</p> <p>Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken. <u>Pericardial effusion and pulmonary hypertension may occur. In addition, necrotising enterocolitis may occur in neonates.</u></p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Serious fluid retention, congestive heart failure, <u>pericardial effusion</u></p> <p>Serious sodium retention, fluid retention, congestive heart failure <u>and pericardial effusion</u> may occur. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures, such as administration of diuretics, should be taken.</p> <p><u>Necrotising enterocolitis</u></p>

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	<p><u>Necrotising enterocolitis may occur in neonates. If symptoms such as vomiting, abdominal distension, diarrhoea, and bloody stool occur, administration of this drug should be discontinued, and appropriate measures should be taken.</u></p>
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.

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