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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**

## Diazoxide

October 12, 2023

### Therapeutic category

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

#### Non-proprietary name

Diazoxide

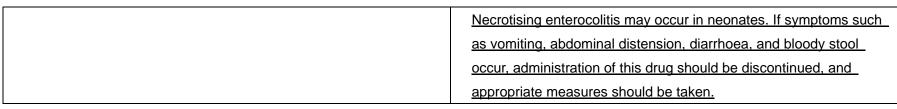
### Safety measure

PRECAUTIONS should be revised.

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



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