



Summary of Investigation Results

Diazoxide

October 12, 2023

Non-proprietary name

Diazoxide

Brand name (marketing authorization holder)

Diazoxide Capsules 25 mg "OP" (OrphanPacific, Inc.)

Japanese market launch

July 2008

Indications

Hyperinsulinaemic hypoglycaemia

Summary of revisions

1. Language concerning pericardial effusion and necrotising enterocolitis should be added to the Pediatric Use section in PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS.
2. "Pericardial effusion" and "necrotising enterocolitis" should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving pericardial effusion or necrotising enterocolitis were evaluated. Cases for which a causal relationship between diazoxide and pericardial effusion or necrotising enterocolitis was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS

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was necessary.

Reference: Number of cases* and patient mortalities involving pericardial effusion or necrotising enterocolitis reported in Japan and overseas

Cases involving pericardial effusion

A total of 6 cases have been reported in Japan to date. (A causal relationship between the drug and event could not be established for these cases.)

No patient mortalities have been reported in Japan to date.

Cases involving necrotising enterocolitis

No cases have been reported in Japan to date.

Cases involving pericardial effusion

A total of 6 cases have been reported overseas to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported overseas to date.

Cases involving necrotising enterocolitis

A total of 15 cases have been reported overseas to date (including 4 cases for which a causal relationship between the drug and event was reasonably possible).

A total of 2 patient mortalities have been reported overseas to date (including 1 case for which a causal relationship between the drug and death subsequent to the event was reasonably possible).

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).