

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

Attachment 1
June 30, 2026

【Therapeutic category】 613 Antibiotic preparations acting mainly on gram-positive and gram-negative bacteria

【Non-proprietary name】 Cefcapene pivoxil hydrochloride hydrate (for pediatric use)

【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>< Children ></u> <u>In children (especially infants), serious hypoglycaemia, convulsions, encephalopathy, etc. associated with hypocarnitinaemia may occur after administration of antibacterials with a pivoxil group including this drug (cefcapene pivoxil hydrochloride hydrate, cefditoren pivoxil, ceftaram pivoxil, tebipenem pivoxil). When selecting drugs, including a process of considering the necessity of this drug, and determining treatment duration, refer to the latest guidelines, etc. Patients' families, etc. should be instructed to immediately seek medical attention if any hypoglycemic symptoms such as convulsions and consciousness disturbed are observed.</u>

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

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

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.