



Summary of Investigation Results

Cefazolin sodium hydrate Cefazolin sodium

August 29, 2023

Non-proprietary name

- a. Cefazolin sodium hydrate
- b. Cefazolin sodium

Brand name (marketing authorization holder)

- a. Cefamezin α 0.25 g for Intramuscular Injection, Cefamezin α 0.5 g for Intramuscular Injection, Cefamezin α 0.25 g for Injection, Cefamezin α 0.5 g for Injection, Cefamezin α 1 g for Injection, Cefamezin α 2 g for Injection, Cefamezin α 1 g for Infusion Kit, Cefamezin α 2 g for Infusion Kit (LTL Pharma Co., Ltd.)
- b. Cefazolin Sodium Injection 1 g Bag Otsuka (Otsuka Pharmaceutical Factory, Inc.), and the others

Japanese market launch

- a. July 1999 (May 1971 for cefazolin sodium preparation)
- b. May 1996

Indications

<Applicable microorganisms>

Cefazolin-susceptible strains of genus *Staphylococcus*, genus *Streptococcus*, *Pneumococcus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, genus *Providencia*

<Applicable conditions>

Sepsis, infective endocarditis, superficial skin infections, deep-seated skin infections,

lymphangitis/lymphadenitis, chronic pyoderma, secondary infections following trauma, thermal burn, and surgical wound, secondary infections of erosions/ulcers, mastitis, osteomyelitis, arthritis, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, lung abscess, pyothorax, secondary infection of chronic respiratory lesions, cystitis, pyelonephritis, peritonitis, cholecystitis, cholangitis, bartholinitis, intrauterine infection, adnexitis, parametritis, endophthalmitis (including panophthalmitis), otitis media, sinusitis, purulent sialoadenitis

Summary of revisions

- a. "Acute coronary syndrome accompanying allergic reaction" should be added to the precaution regarding shock, anaphylaxis in the IMPORTANT PRECAUTIONS section.
- b. "Acute coronary syndrome accompanying allergic reaction" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases involving acute coronary syndrome accompanying allergic reaction reported in Japan were evaluated. Cases for which a causal relationship between cefazolin and acute coronary syndrome accompanying allergic reaction was reasonably possible have been reported in Japan. 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 was necessary.

Reference: Number of cases* and patient mortalities involving acute coronary syndrome accompanying allergic reaction reported in Japan

A total of 7 cases have been reported to date. (A causal relationship between the drug and event was reasonably possible for these cases.)

No patient mortalities have been reported to date.

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



Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

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).

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp