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.

Summary of Investigation Results

Cefoperazone sodium/sulbactam sodium

October 12, 2021

Non-proprietary name

Cefoperazone sodium/sulbactam sodium

Branded name (Marketing authorization holder)

Sulperazon for Intravenous Use 0.5 g, 1 g, Sulperazon Kit for Intravenous Use 1 g (Pfizer Japan Inc.), and the others

Indications

<Applicable microorganisms>

Cefoperazone sodium/sulbactam sodium-susceptible strains of genus *Staphylococcus*, *Escherichia coli*, genus *Citrobacter*, genus *Klebsiella*, genus *Enterobacter*, genus *Serratia*, genus *Proteus*, genus *Providencia rettgeri, Morganella morganii, Haemophilus influenza, Pseudomonas aeruginosa*, genus *Acinetobacter*, genus *Bacteroides*, and genus *Prevotella* species

<Applicable conditions>

Sepsis, infective endocarditis, secondary infections following trauma, thermal burn, and surgical wound, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, lung abscess, pyothorax, secondary infection of chronic respiratory lesions, cystitis, pyelonephritis, peritonitis, intra-abdominal abscess, cholecystitis, cholangitis, liver abscess, bartholinitis, intrauterine infection, uterine adnexitis, parametritis

Summary of revisions

1. “Acute coronary syndrome accompanying allergic reaction” should be added to the precaution regarding shock, anaphylaxis in the IMPORTANT PRECAUTIONS section.
2. “Shock, anaphylaxis (dyspnoea, etc.)” in the Clinically Significant Adverse Reactions

section should be revised to “Shock, anaphylaxis (dyspnoea, etc.), acute coronary syndrome accompanying allergic reaction.”

Investigation results and background of the revision

Cases of acute coronary syndrome accompanying allergic reaction have been reported in patients treated with cefoperazone sodium/sulbactam sodium in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 2 cases involving acute coronary syndrome accompanying allergic reaction have been reported to date. (A causal relationship between the drug and event was reasonably possible for these cases.)

1 instance of patient mortality has been reported to date. (A causal relationship between the drug and death subsequent to the event was reasonably possible for this case.)

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).