Summary of Investigation Results

Tazobactam/piperacillin hydrate

October 6, 2020

Non-proprietary name

Tazobactam/piperacillin hydrate

Branded name (Marketing authorization holder)

Zosyn Intravenous Injections 2.25, 4.5, Zosyn Intravenous Infusions Bag 4.5 (TAIHO Phamaceutical Co., Ltd.), and the others

Indications

1. General infection

   <Applicable microorganisms>

   Tazobactam/piperacillin hydrate-susceptible strains of genus *Staphylococcus*, genus *Streptococcus*, genus *Pneumococcus*, genus *Enterococcus*, *Moraxella (Branhamella) catarrhalis*, *Escherichia coli*, genus *Citrobacter*, genus *Klebsiella*, genus *Enterobacter*, genus *Serratia*, genus *Proteus*, genus *Providencia*, *Haemophilus influenzae*, *Pseudomonas aeruginosa*, genus *Acinetobacter*, genus *Peptostreptococcus*, genus *Clostridium* (excluding *Clostridium difficile*), genus *Bacteroides*, and genus *Prevotella*.

   <Applicable conditions>

   Sepsis, deep-seated skin infections, secondary infections following erosion or ulcer, pneumonia, pyelonephritis, complicated cystitis, peritonitis, intra-abdominal abscess, cholecystitis, and cholangitis.

2. Febrile neutropenia

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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 revisions

"Hypokalaemia" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of hypokalaemia have been reported in patients treated with tazobactam/piperacillin hydrate 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 5 cases involving hypokalaemia have been reported to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).
No patient mortalities have been reported to date.

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).

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