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

Linezolid

February 15, 2024

Non-proprietary name

Linezolid

Brand name (marketing authorization holder)

Zyvox Tablets 600 mg, Zyvox Injection 600 mg (Pfizer Japan Inc.), and the others

Japanese market launch

May 2001

Indications

・<Applicable microorganisms>

Linezolid-susceptible strains of methicillin-resistant *Staphylococcus aureus* (MRSA)

<Applicable conditions>

Sepsis, deep-seated skin infections, chronic pyoderma, secondary infections following trauma, thermal burn, surgical wound, etc., pneumonia

•<Applicable microorganisms>

Linezolid-susceptible strains of vancomycin-resistant *Enterococcus faecium*

<Applicable conditions>

Infections

Summary of revisions

“Rhabdomyolysis” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Pharmaceuticals and Medical Devices Agency

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Investigation results and background of the revision

Cases involving rhabdomyolysis were evaluated. Cases for which a causal relationship between linezolid and rhabdomyolysis 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 was necessary.

Reference: Number of cases* and patient mortalities involving rhabdomyolysis reported in Japan and overseas

A total of 3 cases have been reported in Japan to date (including 1 case for which a causal relationship between the drug and event was reasonably possible).
One instance of patient mortality has been reported in Japan to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)
A total of 7 cases have been reported overseas to date†. (A causal relationship between the drug and event was reasonably possible for 5 cases, including 1 case in which the drug was administered outside the approved dosage and administration.)
No patient mortalities have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports
†Cases which were presented as the basis for a revision of Company Core Data Sheet by the marketing authorization holder

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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