



Summary of Investigation Results

Teicoplanin

May 13, 2022

Non-proprietary name

Teicoplanin

Brand name (Marketing authorization holder)

Targocid 200 mg for Injection (Sanofi K.K.), and the others

Indications

<Applicable microorganisms>

Teicoplanin-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, pyothorax, and secondary infection of chronic respiratory lesions

Summary of revisions

“Acute generalised exanthematous pustulosis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

As a result of evaluating cases reported in Japan and overseas as well as consultation with expert advisers, MHLW/PMDA concluded that revision of precautions in the package insert was necessary.

Number of cases of acute generalised exanthematous pustulosis during the previous 3 fiscal years among the evaluated cases is as follows:

- No cases have been reported in Japan to date.

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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.

• A total of 2 cases have been reported overseas to date (including 1 case 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).