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

Daptomycin

October 18, 2016

Non-proprietary name

Daptomycin

Brand name (Marketing authorization holder)

Cubicin I.V. 350 mg (MSD K.K.)

Indications

Applicable microorganisms

Daptomycin-susceptible methicillin-resistant *Staphylococcus aureus* (MRSA)

Applicable conditions

Sepsis, infective endocarditis, deep skin infection, secondary infection in trauma, burns, or surgical wound, and secondary infection in erosion or ulcer

Summary of revision

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

Background of the revision and investigation results

Cases of acute generalized exanthematous pustulosis have been reported in patients treated with daptomycin both in Japan and overseas. In addition, the company core datasheet (CCDS)* has been updated. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 2 cases associated with acute generalized exanthematous pustulosis has been reported (including one case for which a causal relationship to the product could not be ruled out). No fatality has yet been reported.

NOTE:

* CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp