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Pharmaceuticals and Medical Devices Agency

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Summary of Investigation Results

Meropenem hydrate

September 9, 2025

Non-proprietary name

Meropenem hydrate

Brand name (marketing authorization holder)

Meropen For I.V. Infusion vial 0.25 g, 0.5 g, Meropen For I.V. Infusion kit 0.5 g (Sumitomo Pharma Co., Ltd.), and the others

Japanese market launch

I.V. Infusion vial 0.25 g, 0.5 g: September 1995
I.V. Infusion kit 0.5 g: June 2001

Indications

•Common infections

<Applicable microorganisms>

Meropenem-susceptible strains of genus *Staphylococcus*, genus *Streptococcus*, *Pneumococcus*, genus *Enterococcus*, *Neisseria meningitidis*, *Moraxella (Branhamella) catarrhalis*, *Escherichia coli*, genus *Citrobacter*, genus *Klebsiella*, genus *Enterobacter*, genus *Serratia*, genus *Proteus*, genus *Providencia*, *Haemophilus influenzae*, genus *Pseudomonas*, *Pseudomonas aeruginosa*, *Burkholderia cepacia*, genus *Bacteroides*, genus *Prevotella*

< Applicable conditions >

Sepsis, deep-seated skin infections, lymphangitis/lymphadenitis, secondary infections following trauma, thermal burn, surgical wound, etc., perianal abscess, osteomyelitis, arthritis, tonsillitis (including peritonsillar abscess), pneumonia, lung abscess, pyothorax, secondary infection of chronic respiratory lesions, complicated cystitis, pyelonephritis, peritonitis, cholecystitis, cholangitis, liver abscess, intrauterine infection, adnexitis, parametritis, purulent meningitis, endophthalmitis (including panophthalmitis), otitis media, sinusitis, cellulitis

around jawbone, jaw inflammation
•Febrile neutropenia

Summary of revisions

"Acute generalised exanthematous pustulosis" should be added to the "11.1 Clinically Significant Adverse Reactions" section of "11. ADVERSE REACTIONS."

Investigation results and background of the revision

Cases involving acute generalised exanthematous pustulosis were evaluated. Cases for which a causal relationship between meropenem hydrate and acute generalised exanthematous pustulosis 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*1 and patient mortalities involving acute generalised exanthematous pustulosis reported in Japan and overseas

A total of 4 cases have been reported in Japan to date (including 2 cases for which a causal relationship between the drug and the event was reasonably possible).
No patient mortalities have been reported in Japan to date.

A total of 10 cases*2have been reported overseas to date (A causal relationship between the drug and the event was reasonably possible for 6 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.

*1 Cases reported with "PT: Acute generalised exanthematous pustulosis" (MedDRA ver. 28.0) were retrieved from those collected in the PMDA's safety database for drugs. Among them, cases describing pustule observation were extracted.
*2 Only the cases reported by the marketing authorization holders of meropenem hydrate were evaluated.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their

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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).