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Translated by Pharmaceuticals and Medical Devices Agency



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions Benzylpenicillin benzathine hydrate Benzylpenicillin potassium **Amoxicillin hydrate** Amoxicillin hydrate/potassium clavulanate Ampicillin hydrate **Ampicillin sodium** Ampicillin sodium/sulbactam sodium Sultamicillin tosilate hydrate **Bacampicillin hydrochloride Piperacillin sodium** Ampicillin hydrate/cloxacillin sodium hydrate Ampicillin sodium/cloxacillin sodium hydrate

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> Published by Ministry of Health, Labour and Welfare



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March 28, 2019

Non-proprietary name

Benzylpenicillin benzathine hydrate, benzylpenicillin potassium, amoxicillin hydrate, amoxicillin hydrate/potassium clavulanate, ampicillin hydrate, ampicillin sodium, ampicillin sodium/sulbactam sodium, sultamicillin tosilate hydrate, bacampicillin hydrochloride, piperacillin sodium, ampicillin hydrate/cloxacillin sodium hydrate, ampicillin sodium/cloxacillin sodium hydrate

Safety measure

Precautions should be revised in the package insert.

The following language in the Contraindications section should be revised (revised language is underlined):

Patients with a history of hypersensitivity to any of the ingredients contained in this product

The language in the Relative Contraindications section should be revised as follows:

Patients with a history of hypersensitivity to penicillin antibiotics

(Note) Excluding preparations for which currently "patients with a history of hypersensitivity to any of the ingredients contained in the product" are contraindicated.

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