



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

Aluminum potassium sulfate hydrate/tannic acid (with saline)

November 27, 2018

Non-proprietary name

Aluminum potassium sulfate hydrate/tannic acid (with saline)

Safety measure

Precautions should be revised in the package insert.

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

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

The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Anaphylaxis:

Symptoms including decreased blood pressure, dyspnea, face oedema or flushing may occur, and cases of progression to anaphylactic shock have been reported. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.