



Summary of Investigation Results

Aluminum potassium sulfate hydrate/tannic acid

November 27, 2018

Non-proprietary name

Aluminum potassium sulfate hydrate/tannic acid

Branded name (Marketing authorization holder)

Zione Injection, Zione Injection/Lidocaine (Mitsubishi Tanabe Pharma Corporation)

Indications

Prolapsed internal hemorrhoids

Summary of revisions

1. A precautionary statement for “patients with a history of hypersensitivity to any of the ingredients contained in this product” should be added in the Contraindication section.
2. “Anaphylaxis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of anaphylaxis have been reported in patients treated with aluminum potassium sulfate hydrate/tannic acid in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 6 cases involving anaphylaxis have been reported to date (including 5 cases for which a causal relationship with the product could not be ruled out.)

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



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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.

One instance of patient mortality has been reported to date (a causal relationship with the product could not be established in this case.)

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