



## Summary of investigation results

### Aluminum potassium sulfate hydrate/Tannic acid

March 21, 2017

#### **Non-proprietary name**

Aluminum potassium sulfate hydrate/Tannic acid

#### **Brand name (Marketing authorization holder)**

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

#### **Indications**

Prolapsed internal hemorrhoids

#### **Summary of revision**

1. “Rectovaginal fistula” that may occur in association with the administration procedure, when the product is injected into the anterior hemorrhoids of women, should be newly added to the Important Precautions section.
2. “Rectovaginal fistula” should be newly added in the Clinically Significant Adverse Reactions section.

#### **Background of the revision and investigation results**

Cases of rectovaginal fistula have been reported in patients treated with aluminum potassium sulfate hydrate/tannic acid in Japan. In addition, rectovaginal fistula may occur in association with the administration procedure. 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.

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

A total of 2 cases of rectovaginal fistula have been reported (including 1 case for which a causal relationship to the product could not be ruled out). No fatality has been reported.