



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

March 21, 2017

Non-proprietary name

Aluminum potassium sulfate hydrate/Tannic acid

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section regarding events that may occur with the administration procedure, the following text should be added (underlined parts are revised):

Rectovaginal fistula: Rectovaginal fistula may occur when injecting into the anterior hemorrhoids in women and in case the injection needle penetrates the entire thickness of the rectal wall and the product is inserted/injected into vaginal and proximity sites, patients should be carefully monitored and appropriate measures such as surgery should be taken.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Rectovaginal fistula: Rectovaginal fistula may occur after administration of this product. Patients should be monitored regularly. If fistula is observed, appropriate measures such as surgery should be taken.

* Aluminum potassium sulfate hydrate/Tannic acid is designated as a drug requiring preparation of a Drug Guide for Patients.