



Summary of investigation results

Laxative drug containing magnesium oxide (Over the counter drugs)

October 20, 2015

Non-proprietary name

Laxative drug containing magnesium oxide (Over the counter drugs)

Brand name (Marketing authorization holder)

Slaria Laxative (ROHTO Pharmaceutical Co., Ltd.), and others

Indications

- Constipation
- Alleviation of following symptoms associated with constipation: skin roughness, pimples, abdominal distension, anorexia (decreased appetite), abnormal intragastric fermentation, heaviness of head, hot flash, and hemorrhoids

Summary of revision

“The elderly” should be added in the Consultation section.

Background of the revision and investigation results

The package insert of the prescription drug containing the same ingredients will be revised. Associated with this, 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 for the over the counter drugs.

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

No case associated with hypermagnesaemia has been reported.