



Summary of Investigation Results

D-Sorbitol (urologic irrigating solution)

October 29, 2019

Non-proprietary name

D-Sorbitol (urologic irrigating solution)

Branded name (Marketing authorization holder)

UromaticS 3% urologic irrigating solution (Baxter Limited)

Indications

Urologic irrigation during transurethral surgeries for prostate or bladder diseases, during or after other urological surgeries

Summary of revisions

“Patients with hereditary fructose intolerance” should be added to the Contraindications section.

Investigation results and background of the revision

The European Medicines Agency (EMA) has contraindicated the use of intravenous injection products containing sorbitol or fructose in patients with hereditary fructose intolerance. Although this drug is a urologic irrigating solution, levels of sorbitol absorption similar to intravenous injection products marketed in Japan are suggested and “patients with hereditary fructose intolerance” is listed under the Contraindications section of the package insert of these injection products. 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.



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.

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

No cases involving adverse reactions related to patients with hereditary fructose intolerance have been reported to date.