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.

Summary of Investigation Results

Intravenous injection preparations containing sorbitol or fructose as excipient

March 19, 2019

Non-proprietary name

*

Branded name (Marketing authorization holder)

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Indications

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Summary of revisions

“Patients with hereditary fructose intolerance” should be added to the Careful Administration section for those intravenous injection products containing sorbitol or fructose as excipient that have not been subjected to a precaution regarding administration to patients with hereditary fructose intolerance. Intravenous injection products containing sorbitol or fructose as active ingredient have already addressed the issue by describing the “patients with hereditary fructose intolerance” in the Contraindications section of their package insert.

Investigation results and background of the revision

Following the reported foreign safety measure taken by the EMA to contraindicate the use of intravenous injection products containing sorbitol or fructose as excipient in patients with hereditary fructose intolerance, the necessity of revising the package inserts of relevant products in Japan was considered based on the clinical conditions of hereditary fructose intolerance, findings from several published papers and other information. MHLW/PMDA

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

concluded that it is appropriate in Japan to add “patients with hereditary fructose intolerance” to the Careful Administration section for intravenous injection products containing sorbitol or fructose as excipient based on the results of their investigation of currently available evidence in consultation with expert advisors, considering, among others, the fact that no cases leading to serious outcomes regarding hereditary fructose intolerance have been found with intravenous injection products containing sorbitol or fructose as excipient.

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

N/A

* Affected products by the measure are difficult to specify by non-proprietary names or indications, since the products investigated contain sorbitol or fructose as excipient.

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp