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Revision of Precautions

Preparations containing sorbitol as excipient (intravenous injections)

March 19, 2019

Non-proprietary name

*

Safety measure

Precautions should be revised in the package insert.

The following language should be added to the Careful Administration section (revised language is underlined):

<u>Patients with hereditary fructose intolerance (fructose, a metabolite produced in the body from D-sorbitol** added to the product as excipient cannot be broken down, which may induce hypoglycemia, hepatic failure, renal failure, etc.)</u>

* 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.

** “D-sorbitol” here should be replaced with "sorbitol" for products with their current package inserts specifying "sorbitol."

† Any existing Drug Guides for Patients for the affected products should be revised. Regarding the products for which such guides have not been prepared, their marketing authorization holders should wait for a contact from PMDA concerning the necessity made

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after the agency is notified of their revised package inserts, and should respond appropriately regarding the products for which preparation of the guide is required.

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