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

Azosemide

August 4, 2016

Non-proprietary name

Azosemide

Brand name (Marketing authorization holder)

Diart Tablets 30 mg, 60 mg (Sanwa Kagaku Kenkyusho Co., Ltd.), and others

Indications

Cardiac-induced edema (congestive cardiac failure), renal-induced edema, and hepatic-induced edema

Summary of revision

“Agranulocytosis and leukopenia” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of agranulocytosis and leukopenia have been reported in patients treated with azosemide in Japan. 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.

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

A total of 4 cases associated with agranulocytosis and leukopenia have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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