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Summary of investigation results

Furosemide

March 22, 2016

Non-proprietary name

Furosemide

Brand name (Marketing authorization holder)

a. Lasix Tablets 10 mg, 20 mg, 40 mg, Lasix Fine Granules 4% (Sanofi K.K.), and the others

b. Lasix Injection 20 mg (Sanofi K.K.), and the others

c. Lasix Injection 100 mg (Sanofi K.K.), and the others

d. Eutensin Capsules 40 mg (Sanofi K.K.)

Indications

a. Hypertension (including essential and renal hypertension, etc.), malignant hypertension, cardiac-induced edema (congestive cardiac failure), renal-induced edema, hepatic-induced edema, pre-menstrual tension, edema due to peripheral vascular disorders, stimulating excretion of urinary calculus

b. Hypertension (including essential and renal hypertension, etc.), malignant hypertension, cardiac-induced edema (congestive cardiac failure), renal-induced edema, hepatic-induced edema, brain edema, stimulating excretion of urinary calculus

c. Oliguria due to acute or chronic renal failure

d. Essential hypertension

Summary of revision

“Interstitial pneumonia” should be newly added in the Clinically significant adverse reaction section

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Background of the revision and investigation results

Cases of interstitial pneumonia have been reported in patients treated with furosemide 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 6 cases associated with interstitial pneumonia have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). Of the 6 cases, 3 fatal cases have been reported (a causal relationship between the product and the fatal outcome could not be established for these patients).

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