



Summary of investigation results

Indapamide

July 7, 2015

Non-proprietary name

Indapamide

Brand name (Marketing authorization holder)

- a. Natrix Tablets 1 and 2 (Kyoto Pharmaceutical Industries, Ltd.)
- b. Tenaxil Tablets 1 mg and 2 mg (Alfresa Pharma Corporation)

Indications

Essential hypertension

Summary of revision

'Toxic epidermal necrolysis' should be added to the oculomucocutaneous syndrome and erythema multiforme exudativum subsection in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of toxic epidermal necrolysis have been reported in patients treated with indapamide 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 case of toxic epidermal necrolysis has been reported (the case for which a causal relationship to the product could not be ruled out). The patient was a fatal case (the case for which a causal relationship to the product could not be ruled out).