This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Imidafenacin

June 3, 2014

Non-proprietary Name

Imidafenacin

Brand Name (Marketing Authorization Holder)

URITOS tablets 0.1 mg, URITOS OD tablets 0.1 mg (Kyorin Pharmaceutical Co., Ltd.)
STAYBLA tablets 0.1 mg, STAYBLA OD tablets 0.1 mg (Ono Pharmaceutical Co., Ltd.)

Indications

Overactive bladder with symptoms of urinary urgency, urinary frequency, and urge urinary incontinence

Summary of revision

'Hepatic dysfunction' should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of hepatic dysfunction have been reported in patients treated with imidafenacin in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package inserts was necessary.

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

A total of 4 hepatic dysfunction cases has been reported (including 2 cases in which causality could not be ruled out). Of the 4 cases, no fatal cases have been reported.

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