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

Dutasteride

October 20, 2015

Non-proprietary name

Dutasteride

Brand name (Marketing authorization holder)

a. Avolve Capsules 0.5 mg (GlaxoSmithKline K.K.)

b. Zagallo Capsules 0.1 mg, 0.5 mg (GlaxoSmithKline K.K.)

Indications

a. Benign prostatic hyperplasia

b. Male pattern hair loss (androgenetic alopecia) in men only

Summary of revision

“Clinically significant adverse reaction” section should be newly added in the package insert, and “hepatic function disorder, jaundice” should be added in the Clinically significant adverse reaction.

Background of the revision and investigation results

Cases of hepatic function disorder and jaundice have been reported in patients treated with dutasteride 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. Avolve Capsules 0.5 mg

A total of 6 cases associated with hepatic function disorder have been reported (including 3 cases for which a causal relationship to the product could not be ruled out).

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Of the 6 cases, 1 fatal case has been reported (a causal relationship between the product and the fatal outcome could not be established for this patient).

b. Zagallo Capsules 0.1 mg, 0.5 mg
No case associated with hepatic function disorder has been reported.

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