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

Finasteride

August 29, 2023

Non-proprietary name

Finasteride

Brand name (marketing authorization holder)

Propecia Tablets 0.2 mg, 1 mg (Organon K.K.), and the others

Japanese market launch

December 2005

Indications

Delaying the progression of male pattern baldness in men

Summary of revisions

1. Precautions concerning suicide-related events should be added to the IMPORTANT PRECAUTIONS section.
2. “Patients with depression, depressed state, or a history of those diseases or patients with a history of suicidal ideation or a suicide attempt” should be added to the PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS section (new instructions) or the Careful Administration section (old instructions).

Investigation results and background of the revision

Cases reported in Japan, the results of disproportionality analysis using the WHO Individual Case Safety Reports (ICSRs) Global Database (VigiBase)*, etc. were evaluated for suicide-related events. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary, taking into consideration the

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

following:

- Cases of suicide-related events for which a causal relationship with finasteride was reasonably possible have not been identified as adverse reactions in Japan. However, IC_{025}† in a disproportionality analysis performed by the PMDA using the dataset of VigiBase as of May 28, 2023 showed the following: Suicidal depression 3.5; suicidal ideation 3.3; completed suicide 1.6; suicidal behavior 1.3; suicidal ideation 0.5; suicide attempt 0.4. Thus, the analysis showed that the number of adverse reactions of these events reported for finasteride was significantly higher than would be expected for the entire database.‡ (See appendix.)
- Several published articles suggested an association between finasteride and suicide-related events (JAMA Dermatol, 2021; 157: 35-42, J Clin Psychopharmacol. 2021; 41: 304-9, etc.).

Reference: Number of cases§ and patient mortalities involving suicide-related events reported in Japan

A total of 7 cases have been reported to date (A causal relationship between the drug and event could not be established for these cases.)

One instance of patient mortality has been reported to date. (A causal relationship between the drug and event could not be established for this case.)

*: VigiBase is the WHO global database of reported potential adverse reactions of medicinal products, developed and maintained by Uppsala Monitoring Center (UMC). The information comes from a variety of sources, and the probability that the suspected adverse reaction is drug-related is not the same in all cases.

†: Lower limit of 95% confidence interval for information component (IC)

‡: The information does not represent the opinion of the WHO or UMC.

§: Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp