



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.

Revision of Precautions

Aripiprazole

Aripiprazole hydrate

January 11, 2018

Non-proprietary name

Aripiprazole, aripiprazole hydrate

Safety measure

Precautions should be revised in the package insert.

In the Important Precautions section, the following text should be added (underlined parts are revised):

While it is possible that these events were due to the primary disease, impulse-control disorder such as pathological gambling (continual repeated gambling even though it has socially disadvantageous consequences, such as destruction of personal life), increased sexual urges, compulsive shopping, and binge eating after taking this drug have been reported. Patients and their families should be given a thorough explanation of the symptoms of impulse-control disorder in advance and instructed to consult a physician if symptoms occur. Moreover, patients should be closely monitored for changes in condition or disease state and appropriate measures should be taken if symptoms occur, such as reducing the dosage or discontinuing administration.