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

Aripiprazole

Aripiprazole hydrate

January 11, 2018

Non-proprietary name

a. Aripiprazole
b. Aripiprazole hydrate

Brand name (Marketing authorization holder)

a. Abilify Tablets 1 mg, 3 mg, 6 mg, 12 mg, Abilify OD Tablets 3 mg, 6 mg, 12 mg, 24 mg, Abilify powder 1%, Abilify oral solution 0.1% (Otsuka Pharmaceutical Co., Ltd. and the others).
b. Abilify prolonged release aqueous suspension for IM injection 300 mg, 400 mg, 300 mg syringe, 400 mg syringe (Otsuka Pharmaceutical Co., Ltd.)

Indications

a.

Abilify Tablets 1 mg, 3 mg, 6 mg, 12 mg, Abilify OD Tablets 3 mg, 6 mg, 12 mg, Abilify powder 1%, Abilify oral solution 0.1%

- Schizophrenia
- Improvement of manic symptoms in patients with bipolar disorder
- Depression, depressed state (limited to patients who have had an inadequate response to conventional treatment)
- Irritability accompanying childhood autism spectrum disorder

Abilify OD Tablets 24 mg:

- Schizophrenia
- Improvement of manic symptoms in patients with bipolar disorder

b.

Schizophrenia

Summary of revision

Precautions regarding “impulse-control disorder” should be newly added in the Important Precautions section.

Background of the revision and investigation results

Precautions regarding impulse-control disorder have been in place in the Other Adverse Reactions section considering the cases of impulse-control disorder reported in patients treated with aripiprazole in Japan and overseas, and the pharmacological properties of the drug (properties of partial agonist for dopamine D_2 and D_3 receptors). Recently, the company core data sheet (CCDS) as well as the US and Australian package inserts have been updated while cases of impulse-control disorder have continued to be reported in Japan and overseas. Following investigation results 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. Aripiprazole

   A total of 4 cases associated with impulse-control disorder have been reported [Note].

   No fatality has been reported.

b. Aripiprazole hydrate

   None

Note: A causal relationship was not evaluated.

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