

Aripiprazole Safety Announcement

May 3, 2016

The U.S. Food and Drug Administration (FDA) is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized.

Aripiprazole is used to treat certain mental disorders, including schizophrenia, bipolar disorder, Tourette's disorder, and irritability associated with autistic disorder. It may also be used in combination with antidepressants to treat depression. Aripiprazole can decrease hallucinations and other psychotic symptoms such as disorganized thinking. It can stabilize mood, improve depression, and decrease the tics of Tourette's disorder.

Although pathological gambling is listed as a reported side effect in the current aripiprazole drug labels, this description does not entirely reflect the nature of the impulse-control risk that has been identified. In addition, other compulsive behaviors associated with aripiprazole have been observed, such as compulsive eating, shopping, and sexual actions. These compulsive behaviors can affect anyone who is taking the medicine. As a result, we are adding new warnings about all of these compulsive behaviors to the drug labels and the patient Medication Guides for all aripiprazole products.

Patients and caregivers should be alert for uncontrollable and excessive urges and behaviors while taking aripiprazole. It is important to talk with a health care professional as soon as possible if you or a family member experiences any of these uncontrollable urges, in order to prevent or limit possible harm. Patients should not suddenly stop taking their aripiprazole medicine without first talking to their health care professional.

Health care professionals should make patients and caregivers aware of the risk of these uncontrollable urges when prescribing aripiprazole, and specifically ask patients about any new or increasing urges while they are being treated with aripiprazole. Closely monitor for new or worsening uncontrollable urges in patients at higher risk for impulse-control problems. These include those with a personal or family history of obsessive-compulsive disorder, impulse-control disorder, bipolar disorder, impulsive personality, alcoholism, drug abuse, or other addictive behaviors. Consider reducing the dose or stopping the medicine if such urges develop.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓ Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓ Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at
<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>.]

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