

FDA Drug Safety Communication: FDA warns about new impulse- control problems associated with mental health drug aripiprazole (Abilify, Abilify Maintena, Aristada)

[05-03-2016]

Safety Announcement



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.

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 we identified. In addition, we have become aware of other compulsive behaviors associated with aripiprazole, 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.

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.

Aripiprazole is available under the brand names Abilify, Abilify Maintena, Aristada, and also as generics.

A search of the [FDA Adverse Event Reporting System \(FAERS\) \(/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm2007060.htm\)](#) database and the medical literature in the 13 years since the approval of the first aripiprazole product (Abilify) in November 2002 identified a total of 184 case reports in which there was an association between aripiprazole use and impulse-control problems. There were 167 U.S. cases, which included adults and children. Pathological gambling was the most common (164 cases), but other compulsive behaviors including compulsive eating, spending or shopping, and sexual behaviors were also reported (see Data Summary). FAERS includes only reports submitted to FDA, so there may be additional cases about which we are unaware. In order to provide context for these drug-associated events, approximately 1.6 million patients received an aripiprazole prescription from U.S. outpatient retail pharmacies during 2015.¹

In the majority of cases, patients with no prior history of the compulsive behaviors experienced uncontrollable urges only after starting aripiprazole treatment. Within days to weeks of reducing the dose or discontinuing aripiprazole, these uncontrollable urges stopped.

We strongly advise health care professionals, patients, and caregivers to report side effects involving aripiprazole (Abilify, Abilify Maintena, Aristada) and other drugs to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

[Facts about Aripiprazole \(Abilify, Abilify Maintena, Aristada\)](#) 

[Additional Information for Patients and Consumers](#) 

[Additional Information for Health Care Professionals](#) 

[Data Summary](#) 

[References](#) 

[en Español \(/Drugs/DrugSafety/ucm499986.htm\)](#)

[Drug Safety Communication \(/downloads/Drugs/DrugSafety/UCM498825.pdf\)](#) (PDF - 69KB)

Related Information

- **[Atypical Antipsychotic Drugs Information](/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094303.htm)**
 (</Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094303.htm>)
- **[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](/Drugs/ResourcesForYou/Consumers/ucm143534.htm)**
 (</Drugs/ResourcesForYou/Consumers/ucm143534.htm>)
- **[Think It Through: Managing the Benefits and Risks of Medicines](/Drugs/ResourcesForYou/Consumers/ucm143558.htm)**
 (</Drugs/ResourcesForYou/Consumers/ucm143558.htm>)

Contact FDA

For More Info

855-543-DRUG (3784)

and press 4

druginfo@fda.hhs.gov (<mailto:druginfo@fda.hhs.gov>)

Report a Serious Problem to MedWatch

Complete and submit the report **Online** (<https://www.accessdata.fda.gov/scripts/medwatch/>).

Download form

(<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>) or call

1-800-332-1088 to

request a reporting form, then complete

and return to the address on the

pre-addressed form, or submit by fax to

1-800-FDA-0178.

More in [Drug Safety and Availability](/Drugs/DrugSafety/default.htm)

(</Drugs/DrugSafety/default.htm>)

[Drug Alerts and Statements](/Drugs/DrugSafety/ucm215175.htm) (</Drugs/DrugSafety/ucm215175.htm>)

[Medication Guides](/Drugs/DrugSafety/ucm085729.htm) (</Drugs/DrugSafety/ucm085729.htm>)

[Drug Safety Communications](/Drugs/DrugSafety/ucm199082.htm) (</Drugs/DrugSafety/ucm199082.htm>)

[Drug Shortages](/Drugs/DrugSafety/DrugShortages/default.htm) (</Drugs/DrugSafety/DrugShortages/default.htm>)



[Postmarket Drug Safety Information for Patients and Providers](/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm)

(</Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm>)



[Information by Drug Class](/Drugs/DrugSafety/InformationbyDrugClass/default.htm) (</Drugs/DrugSafety/InformationbyDrugClass/default.htm>)

[Medication Errors](/Drugs/DrugSafety/MedicationErrors/default.htm) (</Drugs/DrugSafety/MedicationErrors/default.htm>)

[Drug Safety Podcasts](/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm) (</Drugs/DrugSafety/DrugSafetyPodcasts/default.htm>)

[Safe Use Initiative](/Drugs/DrugSafety/SafeUseInitiative/default.htm) (</Drugs/DrugSafety/SafeUseInitiative/default.htm>)



[Drug Recalls](/Drugs/DrugSafety/DrugRecalls/default.htm) (</Drugs/DrugSafety/DrugRecalls/default.htm>)

[Drug Supply Chain Integrity](/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm) (</Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm>)

visited on 9/22/2017

