

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

Safety Announcement

[05-03-2016] 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.

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 \(FAERS\)](#) 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)

- Aripiprazole is used to treat certain mental disorders, such as 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 an atypical antipsychotic; however, it works somewhat differently than the other medicines in its drug class. Most atypical antipsychotics more fully block dopamine receptors in the brain, while aripiprazole only partially blocks the activity of these receptors.
- Aripiprazole is available under the brand names Abilify, Abilify Maintena, Aristada, and also as generics.
- Common side effects of aripiprazole include dizziness, lightheadedness, drowsiness, excess saliva/drooling, blurred vision, weight gain, constipation, feeling the urge to move constantly, and trouble sleeping.

- In 2015, approximately 7.7 million prescriptions for oral aripiprazole were dispensed and approximately 1.6 million patients received a dispensed prescription for oral aripiprazole from U.S. outpatient retail pharmacies.¹

Additional Information for Patients and Caregivers

- Rare but serious impulse-control problems, such as pathological gambling, compulsive eating, compulsive shopping, and compulsive sexual behavior have been reported in patients treated with aripiprazole. These uncontrollable and excessive behaviors may result in harm to the patient and others if left unrecognized. These uncontrollable urges were reported to have stopped when the dose was reduced or the medicine was discontinued.
- Talk to your health care professional right away if while taking aripiprazole you or a family member develops new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges that seem out of the ordinary. Patients should not suddenly stop taking their aripiprazole medicine without first talking to their health care professional.
- Read the patient [Medication Guide](#) you receive along with your aripiprazole prescriptions, which explains the risks associated with the use of aripiprazole.
- Talk to your health care professional if you have questions or concerns about aripiprazole.
- Report any side effects from aripiprazole (Abilify, Abilify Maintena, Aristada, and generics) to your health care professional and the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of this page.

Additional Information for Health Care Professionals

- Serious impulse-control problems, particularly pathological gambling, have been reported in patients treated with aripiprazole. These uncontrollable urges were reported to have stopped when the dose was reduced or the medicine was discontinued.
- Other uncontrollable urges reported less frequently than gambling include compulsive sexual behaviors, compulsive spending or shopping, binge or compulsive eating, and other urges with impulsive and compulsive features.
- Make patients and caregivers aware of the possibility of these uncontrollable urges when prescribing aripiprazole, and specifically ask patients about any new or increasing urges while they are being treated with it.
- Advise patients to talk with their health care professional right away if they experience new or increasing impulsive or compulsive behaviors while on treatment.
- Consider lowering the dose or stopping aripiprazole if a patient develops new or increased impulsive or compulsive behaviors.
- Encourage patients to read the patient [Medication Guide](#) they receive with their aripiprazole prescriptions.

- Report adverse events involving aripiprazole (Abilify, Abilify Maintena, Aristada, and generics) to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of this page.

Data Summary

A search of the FDA Adverse Event Reporting System (FAERS) database and the medical literature since the approval of the first aripiprazole product (Abilify) in November 2002 through mid-January 2016 identified 184 case reports (167 FAERS cases and 17 medical literature cases) indicating an association between aripiprazole and impulse-control problems. The specific impulse-control problems reported include: pathological gambling (n=164); compulsive sexual behavior (n=9); compulsive buying (n=4); compulsive eating (n=3); and multiple impulse-control problems (n=4).

All 167 FAERS cases reported that the patients experienced new urges leading to compulsive behavior only after starting aripiprazole treatment, and within days to weeks of reducing the dose or discontinuing aripiprazole treatment, all of these 167 patients reported that the intense urges resolved. None of the 167 patients had a history of pathological gambling, compulsive sexual behavior, binge eating, or compulsive shopping prior to starting aripiprazole treatment. Additionally, none of the 167 patients had concurrent substance abuse disorder (including alcohol use disorder) or symptoms of mania (such as rapid speech, feelings of grandiosity, or reduced need for sleep) at the time they developed impulse-control problems. Reasons for aripiprazole treatment reported in the cases included, but were not limited to, schizophrenia, schizoaffective disorder, bipolar mood disorder, major depressive disorder, and anxiety disorders.

Of the 17 cases published in the medical literature, all cases contained information that the compulsive behavior resolved completely when aripiprazole was discontinued, and four cases reported the return of compulsive behaviors when aripiprazole was restarted. These four cases described a close temporal relationship, within days to weeks, of initiating aripiprazole and the onset of hypersexual behavior (n=3) or pathological gambling (n=1). The patients who experienced hypersexual behavior noticed the behavior when they first started aripiprazole, hypersexuality resolved after discontinuing the drug, and then reappeared after restarting it. In the case describing pathological gambling, the patient experienced an escalation in gambling after starting aripiprazole. The patient was able to significantly reduce his gambling after discontinuing the drug, but uncontrollable urges to gamble returned after he was restarted on aripiprazole.

References

1. IMS Health, National Prescription Audit (NPA) and Total Patient Tracker (TPT), Y2015, Extracted APR 216