

Abilify (aripiprazole)

FDA ALERT [04/2005] Abilify is a type of medicine called an atypical antipsychotic. FDA has found that older patients treated with atypical antipsychotics for dementia had a higher chance for death than patients who did not take the medicine. This is not an approved use.

Brand and Generic Names:

Bristol–Myers Squibb (BMS) manufactures, and BMS and Otsuka Pharmaceuticals market aripiprazole under the brand name Abilify®.

Available forms...

- Abilify® tablets
 - 2 mg
 - 5 mg
 - 10 mg
 - 15 mg
 - 20 mg
 - 30 mg
- Abilify DISCMELT™
 - 10 mg

- 15 mg

- Generic name = aripiprazole

What is the most important information I should know about Abilify?

- Treatment with aripiprazole can improve symptoms of schizophrenia such as: hallucinations, delusions, and disorganized thinking; in some people, improvement in social isolation, reduced speech productivity and motivation may also occur.
- Do not stop taking aripiprazole or change your dose without talking to your healthcare provider first.
- Treatment with aripiprazole is usually well tolerated. However, common adverse effects include: headache, upset stomach, constipation, nervousness, insomnia, and dizziness.
- The atypical antipsychotics have warnings for the possibility that the following adverse effects may occur: diabetes, increases in blood cholesterol/triglycerides.

What is Abilify?

Aripiprazole is an "atypical" antipsychotic medication approved for the treatment of schizophrenia by the FDA in 2002. Aripiprazole helps manage positive symptoms (e.g., hallucinations, delusions, and thought disturbances) as well as negative symptoms (e.g., social withdrawal, inability to experience pleasure, and blunted affect) of schizophrenia. Aripiprazole is also being studied for the treatment of acute mania in bipolar disorder.

What should I discuss with my healthcare provider before taking Abilify?

- Which symptoms of schizophrenia or bipolar disorder are most bothersome to you.
- Tell your doctor if you have thoughts of suicide.
- The medications you have taken in the past. It would be helpful for your provider to know which medications were effective and which were not.
- If you had any serious side effects to other antipsychotic medications like dystonia, tardive dyskinesia, neuroleptic malignant syndrome, weight gain, or diabetes, tell your healthcare provider.
- If you have ever had seizures.
- All other medications you are currently taking.
- If you smoke cigarettes, use illegal drugs, or drink alcohol.

- About any medication allergies you have.
- If you are pregnant, plan to get pregnant, or are breast feeding.

How should I take Abilify?

- Aripiprazole is usually taken once daily. The usual starting dose is 15 mg and the dose should be increased for each individual patient slowly over time.
- Aripiprazole can be taken with or without food.
- Use a calendar or pill box to help you remember to take your medication. Or, have a family member or friend remind you check in with you to be sure you are taking your medication.
- The dose that is right for you will be determined by you and your healthcare provider. Most patients take 30 mg/day or less.

What happens if I miss a dose?

If a dose of aripiprazole is missed, take it as soon as you remember it, if it is not too close to when your next dose is due—discuss this with your health care provider. Do not double your next dose or take more than what is prescribed.

What happens if I overdose?

- If an overdose occurs, whether intentional or accidental, immediate medical attention is necessary. Call your doctor or emergency medical service (911).
- Little information is available for aripiprazole overdoses, and which symptoms to expect. However, sedation and vomiting have been reported. Additionally, you may experience certain common adverse effects in an especially strong way. Common adverse effects include: headache, nervousness, insomnia, and dizziness.

What should I avoid while taking Abilify?

- Avoid smoking cigarettes, using illegal drugs, or drinking alcohol.
- Some people get drowsy on aripiprazole, avoid driving a car until you are sure how the medication will affect you.
- Any herbal or natural supplement.

What are the possible side effects and long-term risks of Abilify?

Aripiprazole has shown a relatively low rate of adverse effects in clinical trials. The most common adverse effects were headache, anxiety, and insomnia. Some people also experience a reduction in blood pressure when they get up from lying or sitting, this is known as "orthostatic hypotension." This can cause dizziness and lightheadedness.

In short-term trials lasting four to six weeks, the incidence of extrapyramidal side effects (abnormal movements, muscle stiffness/shaking, or an uncomfortable restless feeling) from Abilify was low and there was no weight gain. Long-term data suggests the same results with weight gain after 52 weeks remaining similar to placebo.

More serious side effects may include diabetes, high cholesterol and triglycerides, or neuroleptic malignant syndrome.

The atypical antipsychotics have been noted to cause weight gain and increase the risk of diabetes. Abilify is a newer medicine so we have less experience with it overall. So far Abilify does not appear to cause much in the way of weight gain. This is something to assess in your risk benefit assessment when comparing this medicine to other medications. More information will be learned about this and other new medicines and NAMI will keep you informed as the science develops.

What other drugs interact with Abilify?

Some antidepressants, such as Prozac (fluoxetine), Paxil (paroxetine) and Luvox (fluvoxamine) may increase the blood levels of aripiprazole. It is possible that patients taking aripiprazole with either of these agents may experience side effects. Medications with similar effects on aripiprazole blood levels include: Biaxin (clarithromycin), erythromycin, Cardizem (diltiazem), Calan (verapamil), Accolate (zafirlukast). Tell your doctor if you begin or discontinue any of these treatments.

Some medications, such as Tegretol (carbamazepine), Dilantin (phenytoin), phenobarbital, or rifampin (Rifadin) may decrease the blood levels of aripiprazole. It is possible that you may experience a decreased effect from aripiprazole if you also take one of these other medications. Medications with similar effects include: Sustiva (efavirenz), Fulvicin (griseofulvin), Mysoline (primidone), Rezulin (troglitazone). Tell your doctor if you begin or discontinue any of these treatments.

How long does it take for Abilify to work?

Aripiprazole, like some of the other newer antipsychotics, affects the neurotransmitters dopamine and serotonin. Older antipsychotics seem to primarily affect only dopamine.

Improvement of some symptoms may be noticed in some patients within a few weeks. The full benefit of aripiprazole may not be seen for 4-6 weeks.

Updated by Heather Brandt, Pharm.D.
(August 2004)



NAMI wishes to thank the [College of Psychiatric and Neurologic Pharmacists](#) for producing this fact sheet.

For further information. Please contact the pharmaceutical company listed below.

Bristol-Myers Squibb Company	P.O. Box 4500 Princeton, NJ 08543-4500	800-321-1335	www.bms.com
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Free or low-cost medications provided by pharmaceutical companies

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

Abilify Rx Assistance Program: 1-800-332-2056