**General Information**

*Abilify (aripiprazole)* is a *serotonin and dopamine antagonist* belonging to the class of second-generation antipsychotics that are often called *atypical* antipsychotics. (Refer to the handout on “Second-Generation Antipsychotics” for an explanation of how these antipsychotics work.) These agents are atypical in that they are significantly different, both in structure and pharmacology, from the older, *typical* antipsychotic medications such as Thorazine (chlorpromazine), Mellaril (thioridazine), and Haldol (haloperidol). The second-generation antipsychotics block both serotonin and dopamine receptors, whereas the typical antipsychotics are mainly dopamine-receptor antagonists. Abilify possesses other unique pharmacological properties that may also confer anti-manic and antidepressant activity.

The U.S. Food and Drug Administration approved Abilify for the treatment of schizophrenia. The use of a medication for its approved indications is called *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of those treatments. Like other second-generation antipsychotics, Abilify is used to treat other psychiatric disorders, including bipolar disorder, schizoaffective disorder, psychotic depression, and psychosis in Alzheimer’s disease and other neuropsychiatric disorders.

**Dosing Information**

The recommended starting dosage for Abilify is 10–15 mg, taken once daily, preferably in the evening or at bedtime. This medication may be taken without regard to meals. The dosage may be increased, usually not before 2 weeks, up to 30 mg/day. Generally, no dosage adjustment is required for seniors, although some patients benefit from a lower starting dosage of 5 mg.
Common Side Effects

Abilify is generally well tolerated, with few bothersome side effects. Common side effects are headache, nausea, vomiting, insomnia, and tremor. In most cases these side effects are transient and are usually gone after the first week or two of therapy.

**Extrapyramidal symptoms** (EPS) are infrequent with Abilify. EPS are neurological disturbances produced in the area of the brain that controls motor coordination. These side effects include muscle rigidity, tremors, drooling, restlessness, a “mask-like” facial expression, shuffling gait, and muscle spasms that result in abnormal posture (dystonia). EPS mimic Parkinson’s disease, and many of the signs and symptoms are common in both conditions. Some patients experience akathisia, which is a subjective sense of restlessness accompanied by fidgeting and inability to sit or stand still. EPS may be managed by decreasing the antipsychotic dosage or adding another medication (anticholinergic medication) to counteract the side effect.

Abilify is weight neutral (similar to Geodon) and will not induce significant weight gain, compared with some other antipsychotics.

Abilify may block a compensatory response—the narrowing of blood vessels—that counterbalances postural change, resulting in a momentary drop in blood pressure when the person rises too rapidly, which may cause dizziness and lightheadedness. This reaction is known as orthostatic hypotension. Patients, especially seniors and those taking antihypertensive medications, need to be cautious and rise slowly to allow their body to adjust to the change in position, avoiding a sudden drop in their blood pressure.

Adverse Reactions and Precautions

Abilify may cause drowsiness and sedation and impair physical coordination and mental alertness. Patients should avoid potentially dangerous activities, such as driving a car or operating machinery, until they are sure that these side effects will not affect their ability to perform these tasks.

**Tardive dyskinesia** (TD) is a potential adverse reaction from antipsychotic medications. It consists of abnormal involuntary movements. It is a potentially irreversible condition that includes “pill-rolling” movements of the fingers, darting and writhing movements of the tongue, lip puckering, facial grimacing, and shoulder or neck movements. The risk of TD associated with second-generation antipsychotics is significantly lower than with conventional antipsychotics. Because Abilify was introduced recently, there are few data available, but the risk of TD is expected to be very low.

**Neuroleptic malignant syndrome** (NMS) is a rare, toxic reaction to antipsychotics. The symptoms are severe muscle stiffness, rigidity, elevated body temperature, increased heart rate and blood pressure, irregular pulse, and profuse sweating. NMS may lead to delirium and coma. It can be fatal if medical intervention is not immediately provided. There are no tests to predict whether an individual is susceptible to developing NMS when exposed to an antipsychotic. Thus NMS must be recognized early because it is a medical emergency that requires immediate discontinuation of the antipsychotic, hospitalization, and intensive medical treatment.

Use in Pregnancy and Breastfeeding: Pregnancy Category C

Abilify has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. In animal studies, there was no evidence of harm to the fetus when exposed to Abilify. Animal studies, however, are not always predictive of effects in humans. Women who are pregnant or may become pregnant should discuss this with their physician. Some women may experience a recurrence of their psychosis when they stop Abilify. In these circumstances, the physician may discuss the need to restart the medication or seek an alternative medication or treatment.
Nursing mothers should not take Abilify, because small amounts will pass into breast milk and be ingested by the baby. If stopping the antipsychotic is not an alternative, breastfeeding should not be started or should be discontinued.

**Possible Drug Interactions**

Some medications when taken together with Abilify may result in drug interactions that alter their levels, which may produce undesired reactions. The possible drug interactions with Abilify are summarized in the table below.

<table>
<thead>
<tr>
<th>Drug Combination</th>
<th>Interactions</th>
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<tbody>
<tr>
<td>Prozac (fluoxetine) or Paxil (paroxetine)</td>
<td>Prozac and Paxil can decrease the metabolism of Abilify, thus increasing Abilify blood levels and the likelihood of unwanted side effects.</td>
</tr>
<tr>
<td>Nizoral (ketoconazole)</td>
<td>Nizoral, an antifungal agent, may decrease the metabolism of Abilify, thus increasing Abilify blood levels and the likelihood of unwanted side effects.</td>
</tr>
<tr>
<td>Tegretol (carbamazepine)</td>
<td>Tegretol can decrease the blood levels of Abilify, making it less effective in treating the symptoms of the illness.</td>
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</tbody>
</table>

Patients taking Abilify should not consume alcohol because the combination may impair thinking, judgment, and coordination.

**Overdose**

There are few data of acute overdose with Abilify. No fatalities have been reported in cases of Abilify overdose; in these cases, the largest identified amount taken was 180 mg, with which the only symptoms were somnolence and vomiting. The outcome may depend on the amount ingested and whether Abilify was combined with other medications.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency department for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

**Special Considerations**

- Do not discontinue your medication without consulting your physician.
- If you miss a dose, take it as soon as possible that day. If into the next day, skip the missed dose and continue on your regular dosing schedule, but do not take double doses.
- Abilify may be taken with or without food.
- Abilify may cause sedation and drowsiness, especially during initiation of therapy, and impair your alertness. Use caution when driving or performing tasks that require alertness.
• Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of the medication.
• Keep your medication out of reach of children.

*If you have any questions about your medication, consult your physician or pharmacist.*

**Notes**