## 2.8 Dosing of Oral Solution

**CYP3A4 Inducers**

Table 2: Dose Adjustments for Aripiprazole in Patients who are known CYP2D6 poor withdrawn, aripiprazole dosage should be reduced to the original level over 1 to 2 weeks. Patients who

<table>
<thead>
<tr>
<th>CYP2D6 Status</th>
<th>Dose Adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor Metabolizers</td>
<td>Administer half of the usual dose.</td>
</tr>
<tr>
<td>CYP3A4 Inducers</td>
<td>Administer a quarter of the usual dose.</td>
</tr>
</tbody>
</table>

## 3.1.2 Management of Overdosage

- **Adults:** Acute overdosage of oral formulations results in an initial phase of rapid and variable absorption followed by a slower absorption. The primary clinical manifestation of acute overdosage is an upset stomach, nausea, vomiting, and abdominal discomfort. 
- **Children:** In the preparation of this product, an attempt was made to limit the risk of serious adverse reactions due to overdosage. However, if an overdose does occur, do not induce emesis or give activated charcoal. Use supportive and symptomatic therapy as needed.

**DOSING GUIDELINES**

- **Initial Dose:** The initial dose of oral formulations is 10 mg/day for adults and adolescents. The dosage should be adjusted according to the patient’s response and tolerance to treatment. 
- **Maintenance Dose:** The maintenance dose of oral formulations is 10-30 mg/day, depending on the patient’s response to treatment. 

**WASHERS AND PRECAUTIONS**

- **Falls:** Avoid antipsychotic treatment for patients with dementia-related psychosis, as this may increase the risk of hospitalization due to falls. 
- **Neuroleptic Malignant Syndrome:** If neuroleptic malignant syndrome develops, discontinue the drug and institute supportive and symptomatic therapy. 

**ADVERSE REACTIONS**

- **Sleep disorders:** Atypical antipsychotics are associated with sleep disorders, including insomnia, somnolence, and sleep attacks. 
- **Neurological adverse reactions:** The most common neurological adverse reactions are extrapyramidal syndrome, dystonia, akathisia, and tremor. 

**DRUG ABUSE AND DEPENDENCE**

- **Withdrawal symptoms:** Patients treated with antipsychotic drugs may experience withdrawal symptoms, including restlessness, agitation, confusion, and difficulty sleeping. 

**USING IN SPECIFIC POPULATIONS**

- **Children:** The safety and efficacy of oral formulations were not evaluated in children younger than 17 years old. 
- **Adolescents:** The safety and efficacy of oral formulations were evaluated in adolescents aged 16-17 years old. 

**HOW SUPPLIED/STORAGE AND HANDLING**

- **Formulations:** Tablets: pink, round, slightly biconvex tablets, engraved “ARI” over “30” on one side and “APO” other side. 
- **Storage:** Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). 

**PATIENT INFORMATION**

- **Dosage and Administration:** Oral formulations: Administer once daily without regard to meals. 
- **Pregnancy:** Pregnancy Category B. 
- **Breastfeeding:** It is not known whether this drug is distributed in human milk. Use caution when breastfeeding. 
- **Pediatric patients:** Safety and efficacy in children younger than 17 years old have not been established. 

**REVISION HISTORY**

- **March 2019:** Revised to reflect the use of new data from the 2019 Otsuka America Pharmaceutical, Inc. study. 
- **March 2018:** Revised to reflect the use of new data from the 2018 Otsuka America Pharmaceutical, Inc. study.
Metabolic Changes

Treatment producing a satisfactory clinical response should be sought. The need for continued treatment in patients who suffer from a chronic illness that (1) is known to respond to antipsychotic drugs and (2) for the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at common, after relatively brief treatment periods at low doses.

A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients commonly, with administration of antipsychotic drugs, including aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis on the other side.

Smaller numbers of patients treated with aripiprazole were included in the Aripiprazole versus Placebo in Schizophrenia and aripiprazole for Adolescents and Young Adults with Schizophrenia studies. Table 6 shows the changes in fasting glucose from placebo-controlled monotherapy studies in adult patients with schizophrenia or another indication (median exposure of 22 days). Table 8 shows the changes in fasting glucose from placebo-controlled trials in pediatric and adolescent schizophrenia and another indication (median exposure of 42 to 43 days).

Table 6: Changes in Fasting Glucose From Placebo-Controlled Monotherapy

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Category</th>
<th>Mean Change From Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-64</td>
<td>Decreases Compared to Placebo</td>
<td>+4.8 mg/dL (with a median exposure of 43 days; N=259)</td>
</tr>
<tr>
<td>18-24</td>
<td>Increases Compared to Placebo</td>
<td>+1.7 mg/dL (with a median exposure of 42 days; N=822)</td>
</tr>
</tbody>
</table>

In these studies, aripiprazole showed efficacy similar to placebo in improving symptoms of schizophrenia; however, the overall number of patients was not sufficient to reach any conclusion about drug effect on suicidality.

In the randomized, double-blind, placebo-controlled Study to Evaluate the Safety Experience in Elderly Patients with Psychosis Associated with Alzheimer's Disease, 32 elderly patients were treated with aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis on the other side.

In a post-hoc analysis, rates of suicidal ideation and behavior in patients with MDD were compared between those who received aripiprazole and those who received placebo. Rates were calculated using a generalized estimating equation model for the number of cases of suicidality per 1,000 patient-years, controlling for the fixed effects of age group and gender. The findings showed that rates of suicidal ideation and behavior were lower in patients who received aripiprazole compared to those who received placebo. No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide. Aripiprazole is not approved for the treatment of depression. The prescriber should be aware that antidepressants, including those with an atypical antipsychotic component, can delay the recurrence of depression.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing therapy, in patients who show signs of exacerbation of a major depressive episode. Such monitoring should include daily assessment for the emergence of difficulty swallowing or excessive somnolence, which could predispose patients to aspiration pneumonia, systemic infection) and untreated or inadequately treated extrapyramidal signs and symptoms (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs and symptoms, which may occur with administration of antipsychotic drugs, including aripiprazole. Rare cases of NMS may occur with administration of antipsychotic drugs, including aripiprazole.

In the worldwide clinical database, there were 29 cases of NMS. Clinical manifestations of NMS have been reported in adult and pediatric patients being treated with antidepressants for MDD as well as for other psychiatric disorders. There has been a reported increased risk of suicide-related outcomes in patients treated with antidepressants for MDD. The results of a post-hoc analysis comparing rates of suicidal ideation and behavior in patients who received aripiprazole and those who received placebo showed that rates of suicidal ideation and behavior were lower in patients who received aripiprazole compared to those who received placebo. No suicides occurred in any of the pediatric trials. There were suicides in the adult trials, but the number was not sufficient to reach any conclusion about drug effect on suicide. Aripiprazole is not approved for the treatment of depression. The prescriber should be aware that antidepressants, including those with an atypical antipsychotic component, can delay the recurrence of depression.

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Aripiprazole has been evaluated for safety in 1,686 patients (6 to 18 years) who participated in aripiprazole. A total of 3,390 patients were treated with oral aripiprazole for at least 180 days and 1,933 patients with oral aripiprazole for at least 52 weeks.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

### 6 ADVERSE REACTIONS

#### PRECAUTIONS (5.1)

Aripiprazole and other antipsychotic drugs may cause sedation, dizziness, and weakness. This may occur in patients with advanced dementia and patients with dementia-related psychosis.

Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic drugs, including aripiprazole. This effect may be decreased in magnitude by adequate hydration and environmental control when indicated. Patients with a history of seizures, hyperpyrexia, or hypothermia should be observed for signs of hyperthermia, especially during periods of stress and other environmental stresses.

#### POTENTIAL FOR COGNITIVE AND MOTOR IMPAIRMENT

In short-term, placebo-controlled trials, patients with a history of seizures excluded from the efficacy analyses were more likely to have an adverse event leading to study withdrawal than patients who did not have a history of seizures (2.1% vs. 0.6%). Patients who have had a head injury, a stroke, or other events that have caused brain trauma may be more susceptible to the development of antipsychotic-induced neuroleptic malignant syndrome. Aripiprazole and other antipsychotics should be used with caution in patients with a history of seizures or hyperpyrexia.

Disorders in judgment, thinking, or motor function may occur during antipsychotic treatment. These disorders may be manifested as abnormalities in the way a patient thinks, the way a patient acts, or both. These disorders may include decreased ability to think or act promptly as a result of antipsychotic treatment. Consider discontinuation of aripiprazole at the first sign of a clinically significant decline in mental, psychological, or physical performance.

#### POTENTIAL FOR NEUTROPENIA

Neutropenia is a potential risk for patients taking aripiprazole. Neutrophil counts should be monitored at regular intervals in patients taking aripiprazole and in patients with a history of a clinically significant low WBC/ANC or drug-induced leukopenia/neutropenia, Possible risk factors for leukopenia/neutropenia include pre-existing low white blood cell count or drug-induced leukopenia.

#### POTENTIAL FOR SEROTONIN SYNDROME

The possibility of a serotonin syndrome, whether severe or not, must be taken into account in the management of patients taking aripiprazole.

The concurrent use of aripiprazole with other serotonergic drugs such as selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tryptophan, selective serotonin reuptake inhibitor (SSRI) monoamine oxidase inhibitors (MAOIs), or other serotonergic drugs (i.e., St. John's wort) is possible. Caution is recommended in such combination treatments, and it is possible that an increased risk of serotonin syndrome may exist.

#### POTENTIAL FOR TARDIVE DYSKINESIA

Tardive dyskinesia is a potentially irreversible neurological syndrome that has been reported in patients treated with antipsychotic drugs. The risk of developing tardive dyskinesia increases with the duration of treatment, the dose of the agent, and the age of the patient. Tardive dyskinesia can occur regardless of the type of antipsychotic treatment and despite any measures to prevent the development of the syndrome, including dosage reduction or discontinuation of treatment.

#### POTENTIAL FOR WEIGHT gain

Increased weight may occur in patients treated with antipsychotic agents, including aripiprazole. The most frequent changes from baseline weight were increases in body weight in pediatric and adolescent patients (6 to 18 years) (Table 15). The increases in body weight occur more frequently in pediatric and adolescent patients (6 to 18 years) than in adult patients (Table 14). The percentage of pediatric and adolescent patients with weight gain ≥7% of body weight is shown in Table 15: Percentage of Patients From Placebo-Controlled Monotherapy Indication Trials. The percentage of adult patients with weight gain ≥7% of body weight is shown in Table 14: Percentage of Patients From Placebo-Controlled Monotherapy Trials in Other Indication.

#### POTENTIAL FOR DYSLIPIDEMIA

Dyslipidemia has been observed in randomized placebo-controlled trials. In an analysis of 13 placebo-controlled monotherapy trials, primarily from pooled schizophrenia and other indications monotherapy trials, there was no significant increase in serum cholesterol levels in patients treated with aripiprazole compared to placebo-treated patients. There was also no significant increase in serum triglyceride levels in patients treated with aripiprazole compared to placebo-treated patients.

#### OTHER INDICATIONS

In an analysis of 17 placebo-controlled monotherapy trials, primarily from pooled schizophrenia and other indications monotherapy trials, patients treated with aripiprazole for up to 42 days had a mean increase in serum triglycerides of 3.7 mg/dL compared to a mean increase in placebo-treated patients of 0.1 mg/dL. In an analysis of 17 placebo-controlled monotherapy trials, primarily from pooled schizophrenia and other indications monotherapy trials, patients treated with aripiprazole for up to 42 days had a mean decrease in serum HDL cholesterol of -0.02 mg/dL compared to a mean increase in placebo-treated patients of +0.1 mg/dL.

#### OTHER INDICATIONS

Table 15 shows the percentage of pediatric and adolescent patients with weight gain ≥7% of body weight by indication. In a pooled analysis of pediatric and adolescent patients (6 to 18 years) treated with aripiprazole, the mean increase in weight gain ≥7% of body weight was 4.7% (95% CI: 3.5, 6.0) compared to placebo (3.7%, 95% CI: 2.5, 4.9) for the main indication (schizophrenia) and 4.7% (95% CI: 2.5, 4.9) compared to placebo (3.7%, 95% CI: 2.5, 4.9) for other indications. The mean increase in weight gain ≥7% of body weight was 7.4% (95% CI: 6.6, 8.3) compared to placebo (6.6%, 95% CI: 5.6, 7.7) for the main indication (schizophrenia) and 7.4% (95% CI: 6.6, 8.3) compared to placebo (6.6%, 95% CI: 5.6, 7.7) for other indications.

#### OTHER INDICATIONS

Table 14 shows the percentage of adult patients with weight gain ≥7% of body weight by indication. In a pooled analysis of adult patients (18 years and older) treated with aripiprazole, the mean increase in weight gain ≥7% of body weight was 4.7% (95% CI: 3.5, 6.0) compared to placebo (3.7%, 95% CI: 2.5, 4.9) for the main indication (schizophrenia) and 4.7% (95% CI: 3.5, 6.0) compared to placebo (3.7%, 95% CI: 2.5, 4.9) for other indications. The mean increase in weight gain ≥7% of body weight was 7.4% (95% CI: 6.6, 8.3) compared to placebo (6.6%, 95% CI: 5.6, 7.7) for the main indication (schizophrenia) and 7.4% (95% CI: 6.6, 8.3) compared to placebo (6.6%, 95% CI: 5.6, 7.7) for other indications.

#### OTHER INDICATIONS

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Adverse Reactions in Long-Term, Double-Blind, Placebo-Controlled Trials

Additional Findings Observed in Clinical Trials

- Dystonia
- Akathisia
- Extrapyramidal Symptoms

Commonly observed adverse reactions associated with the use of aripiprazole in adolescent patients include:

- Rash
- Asthenia
- Pyrexia
- Constipation
- Abdominal Pain Upper
- Salivary Hypersecretion
- Nausea
- Vomiting
- Blurred Vision
- Dizziness
- Headache

Commonly Observed Adverse Reactions in Pediatric Patients (6 to 18 years) with Schizophrenia, or Other Indications

- Fatigue
- Somnolence
- Dystonia
- Akathisia
- Dizziness
- Headache

Less Common Adverse Reactions in Pediatric Patients (6 to 18 years) with Schizophrenia, or Other Indications

- Other Indications

- Rash
- Asthenia
- Pyrexia
- Constipation
- Abdominal Pain Upper
- Salivary Hypersecretion
- Nausea
- Vomiting
- Blurred Vision
- Dizziness
- Headache

Preferred Term

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Preferred Term</th>
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<tbody>
<tr>
<td>Gastrointestinal Disorders</td>
<td>Nausea, vomiting</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
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<td>Gastrointestinal Disorders</td>
<td>Headache</td>
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Percentage of Patients Reporting

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<th>System Organ Class</th>
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<td>Headache</td>
</tr>
</tbody>
</table>

Dose-Related Adverse Reactions

Dose response relationships for the incidence of treatment-emergent adverse events were evaluated. The adverse reactions detailed in the tables that follow were reported by at least 1% of patients treated with aripiprazole 10 mg/day, unless otherwise specified. These reactions are listed in descending order of frequency associated with each dose level among all trials of aripiprazole 18 mg/day or above and placebo. Among aripiprazole 10 mg/day or below, the adverse reactions reported by at least 1% of patients treated with aripiprazole, except for tremor, were:

- Rash
- Asthenia
- Pyrexia
- Constipation
- Abdominal pain upper
- Salivary hypersecretion
- Nausea
- Vomiting
- Blurred vision
- Dizziness
- Headache

Other Indications

<table>
<thead>
<tr>
<th>System Organ Class</th>
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</tr>
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<td>Other Indications</td>
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Percentage of Patients Reporting

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Other Indications

- Other Indications

- Rash
- Asthenia
- Pyrexia
- Constipation
- Abdominal pain upper
- Salivary hypersecretion
- Nausea
- Vomiting
- Blurred vision
- Dizziness
- Headache
Common adverse reactions (reported in at least 5% of all overdose cases) reported with oral aripiprazole alone. The largest known dose with a known outcome involved acute ingestion of 1260 mg of oral aripiprazole alone and in combination with other substances. No fatality was reported with aripiprazole.

OVERDOSAGE

The extent to which a CNS-active drug will be misused, diverted, and/or abused once marketed. In physical dependence studies in monkeys, withdrawal symptoms were observed upon abrupt cessation of the drug, including tremor, convulsions, nystagmus, and increased brain and pituitary gland weights. Aripiprazole has not been systematically studied in humans for its potential for abuse, tolerance, or dependence (development of tolerance, increases in dose, drug-seeking behavior).

9.3 Dependence

Aripiprazole has not been systematically studied in humans for its potential for abuse, tolerance, or dependence (development of tolerance, increases in dose, drug-seeking behavior).

4.6 Pregnancy

Data

Information describing a clinical study in which efficacy was not demonstrated in patients ages 6 to 12 years is approved for Otsuka America Pharmaceutical, Inc.’s ABILIFY.

Additional pediatric use information is approved for Otsuka America Pharmaceutical, Inc.’s ABILIFY.

Additional pediatric use information is approved for Otsuka America Pharmaceutical, Inc.’s ABILIFY.

Boxed Warning

Aripiprazole has not been systematically studied in humans for its potential for abuse, tolerance, or dependence (development of tolerance, increases in dose, drug-seeking behavior).

8.7 ADMINISTRATION

Metabolize CYP2D6 substrates and are classified as poor metabolizers (PM).

Aripiprazole is present in human breast milk. Because of the potential for serious adverse reactions in nursing infants from aripiprazole, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

The effect of aripiprazole on labor and delivery in humans is unknown.

9.2 Drug Interactions

Specifically, the potential for an increase in aripiprazole exposure after co-administration with strong CYP2D6 inhibitors (e.g., fluoxetine, paroxetine, venlafaxine) should be considered.

Monitor blood pressure and pulse in patients receiving antihypertensive medications concomitantly with aripiprazole.

An increase in aripiprazole exposure after co-administration with strong CYP2D6 inhibitors (e.g., fluoxetine, paroxetine, venlafaxine) should be considered.

Additional pediatric use information is approved for Otsuka America Pharmaceutical, Inc.’s ABILIFY.

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HOW SUPPLIED/STORAGE AND HANDLING

Doses statistically significantly superior to placebo.

than the 10 mg/day dose. Although maintenance efficacy in pediatric patients has not been systematically

doses of aripiprazole were superior to placebo in the PANSS total score (Study 6 in Table 26), the

Pediatric Patients

scores ≥5 (moderately severe) on the hostility or uncooperativeness items of the PANSS, or ≥20%

Relapse during the double-blind phase was defined as CGI-Improvement score of ≥5 (minimally worse),

who were, by history, symptomatically stable on other antipsychotic medications for periods of 3

An examination of population subgroups did not reveal any clear evidence of differential

the 10 mg dose of aripiprazole was superior to placebo in the PANSS total score (Study 4 in Table 26),

positive subscale, PANSS negative subscale, and CGI-severity score.

The Clinical Global Impression (CGI) assessment reflects the impression of a skilled observer, fully

schizophrenia (7 items), negative symptoms of schizophrenia (7 items), and general psychopathology

Syndrome Scale (PANSS). The PANSS is a 30 item scale that measures positive symptoms of

a phase-II study for aripiprazole in the treatment of schizophrenia, patients were treated for 8 to 14 weeks,

with aripiprazole, hemodialysis is unlikely to be useful in overdose management since aripiprazole is

by 50%.

with aripiprazole, partially preventing the absorption of aripiprazole. Administration of 50 g of activated charcoal, one

hypotension, lethargy, loss of consciousness, QRS complex prolonged, QT prolonged, pneumonia

aripiprazole overdosage (alone or in combination with other substances) include vomiting, somnolence,

aripiprazole and aripiprazole sulfone are highly bound to plasma proteins. The mean plasma protein binding of

Formulations

Aripiprazole tablets.

Pharmacokinetic studies showed that aripiprazole orally disintegrating tablets are bioequivalent to

Aripiprazole activity is presumably primarily due to the parent drug, aripiprazole, and to a lesser extent,

serotonin 5-HT_1A_ receptors and antagonist activity at 5-HT_2A_ receptors.

difference (drug minus placebo) in least-squares mean change from baseline.

n=68 per study, 2 mg and 5 mg doses.

n=68 per study, 1 mg, 3 mg, and 10 mg doses.

Table 7: Aripiprazole tablets.

Figure 6: Kaplan-Meier Estimation of Cumulative Proportion of Patients with Relapse

* Doses statistically significantly superior to placebo.
What should I avoid while taking aripiprazole?

Pharmacist when you get a new medicine. Know the medicines you take. Keep a list of your medicines to show your healthcare provider and aripiprazole works. Aripiprazole may affect the way other medicines work, and other medicines may affect how aripiprazole works.

What is aripiprazole?

Call a healthcare provider right away if you or your family member has any of the following symptoms:

Uncontrolled body movements (tardive dyskinesia). Because aripiprazole may have the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably sure they do not have these symptoms.

If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider. Unusual urges include: binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges.

See Medication Guide

17 PATIENT COUNSELING INFORMATION

Controlled Room Temperature.

Store at 20ºC to 25ºC (68ºF to 77ºF); excursions permitted from 15ºC to 30ºC (59ºF to 86ºF) [see USP Controlled Room Temperature].

16.2   Storage

Tablets

Bottles of 1,000 (NDC 60505-2677-8)

Bottles of 30 (NDC 60505-2676-3)

Bottles of 30 (NDC 60505-2675-3)

Bottles of 30 (NDC 60505-3075-3)

16.1   How Supplied

What are the possible side effects of aripiprazole?

Dizziness

You can watch for these side effects and try to prevent them:

Drowsiness

These are not all the possible side effects of aripiprazole. These side effects are not the only ones that can happen, and there may be others. Call your healthcare provider if you have any side effect that is not listed here, or if you are still having side effects of aripiprazole and you think they are not going to go away.

If you have any questions about the side effects of aripiprazole, ask your healthcare provider or pharmacist.

Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider if you have any of these symptoms of high blood sugar while receiving aripiprazole: thirst, urination that is more frequent or larger than normal, hunger, fatigue, feeling weak or tired, feeling hungry, feeling lightheaded or feeling confused.

Call your healthcare provider if you have any of these symptoms of high blood sugar while receiving aripiprazole: feeling weak or tired, dizziness, confusion, sweating, changes in body temperature, refusal to eat, vomiting, breathing difficulty, and being unable to wake up. These symptoms may indicate a medical emergency.

Side effects can include:

A constellation of symptoms, described as hyperactivity and changes in cognitive functioning, may occur in children and adolescents who are started on aripiprazole or whose dose is increased rapidly. Some of these symptoms may be more severe than the patient's baseline condition, and they may include:

Dizziness

Dizziness and possible fainting

Stiff muscles

Unusual excitement

Uncontrolled body movements (tardive dyskinesia).

Aripiprazole can raise the risk of death in elderly people who have lost touch with reality due to their mental illness. Aripiprazole is not approved for use in these patients.

Antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions:

Risk of suicidal thoughts or actions:

Suicidal thoughts or actions:

You can watch for these side effects and try to prevent them:

Depression and other serious mental illnesses, and suicidal thoughts or actions:

Call your healthcare provider if you have any of these symptoms of high blood sugar while receiving aripiprazole: feeling weak or tired, dizziness, confusion, sweating, changes in body temperature, refusal to eat, vomiting, breathing difficulty, and being unable to wake up. These symptoms may indicate a medical emergency.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member:

Suicidal thoughts or actions:

Depression and other serious mental illnesses, and suicidal thoughts or actions:

If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider. Unusual urges include: binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges.

Call a healthcare provider right away if you or your family member has any of the following symptoms:

Suicidal thoughts or actions:

Depression and other serious mental illnesses, and suicidal thoughts or actions:

Call a healthcare provider right away if you or your family member has any of the following symptoms:

Suicidal thoughts or actions:

What are the possible side effects of aripiprazole?

Dizziness

Drowsiness

Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole can cause lightheadedness or fainting when you suddenly stand up, especially if you are elderly. To avoid lightheadedness or fainting, get up slowly from a sitting or lying position. Be careful when you get up from a sitting or lying position.

Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole may cause you to feel tired or lose your energy. Do not drive or operate heavy machinery if you have these side effects. These side effects may be more likely to occur if you are already tired, weak, or thin. Talk to your healthcare provider about the proper way to treat any medical condition you have, such as diabetes.

Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole may make you feel weak or tired. It is important for you to drink water to avoid dehydration, especially if you exercise a lot or are in an area that is very hot. Aripiprazole may cause you to feel tired or lose your energy. Do not drive or operate heavy machinery if you have these side effects. Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.

Aripiprazole affects you. Aripiprazole may make you drowsy. Be careful driving or operating machinery until you know how this medicine affects you.
The most common side effects of aripiprazole in children include:
- feeling sleepy
- headache
- vomiting
- fatigue
- increased or decreased appetite
- increased saliva or drooling
- insomnia
- nausea
- stuffy nose
- weight gain
- uncontrolled movement such as restlessness, tremor, muscle stiffness

These are not all the possible side effects of aripiprazole. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store aripiprazole tablets?
Store at 20ºC to 25ºC (68ºF to 77ºF).
Keep aripiprazole tablets and all medicines out of the reach of children.

General information about the safe and effective use of aripiprazole. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use aripiprazole for a condition for which it was not prescribed. Do not give aripiprazole to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about aripiprazole tablets that was written for healthcare professionals.

What are the ingredients in aripiprazole tablets?
Active ingredient:
aripiprazole
Inactive ingredients:
- croscarmellose sodium
- microcrystalline cellulose
- magnesium stearate
- tartaric acid. Colorants include Indigotine Aluminum Lake (FD&C Blue no. 2) (for 2 mg and 5 mg), iron oxide red (for 10 mg and 30 mg) and iron oxide yellow (for 2 mg and 15 mg).

Additional pediatric use information is approved for Otsuka America Pharmaceutical, Inc.'s ABILIFY® (aripiprazole) product. However, due to Otsuka America Pharmaceutical, Inc.'s marketing exclusivity rights, this drug product is not labeled with that information.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Call your doctor for medical advice about side effects. You may report side effects to Apotex Corp. at 1-800-706-5575 or to FDA at 1-800-FDA-1088.

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ARIPIPRAZOLE TABLETS, USP
2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg
Manufactured by
Manufactured for
Apotex Inc.
Apotex Corp.
Toronto, Ontario
Weston, Florida
Canada M9L 1T9
USA 33326
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