

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

**Pr**ABILIFY®  
**Aripiprazole Tablets**

Read this carefully before you start taking **ABILIFY** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ABILIFY**.

**Serious Warnings and Precautions**

ABILIFY belongs to a group of medicines called atypical antipsychotics. These medicines have been linked to a higher rate of death when used in elderly patients with dementia (which is the loss of memory and other mental abilities).

ABILIFY is not to be used if you are elderly and have dementia.

**What is ABILIFY used for?**

ABILIFY is used for the treatment of schizophrenia in adults and in adolescents (15-17 years of age). Not all people with this disorder have the same symptoms. Some of the most common symptoms of schizophrenia may include:

- hallucinations (seeing, feeling, hearing or smelling things that are not there)
- delusions (believing things that are not true)
- paranoia (not trusting others or feeling very suspicious)
- avoiding family members and friends and wanting to be alone
- feeling depressed, anxious or tense

ABILIFY is also used to treat adults and adolescent patients (13-17 years of age) who suffer from manic or mixed episodes in bipolar I disorder. Bipolar disorder is a condition with symptoms such as:

- feeling invincible or an all powerful inflated self-esteem
- having racing thoughts, easily losing train of thought
- overreacting to what you see or hear
- misinterpreting events
- speeding-up your activities, talking very quickly, too loudly, or more than usual
- needing less sleep
- having poor judgment
- severe irritability

ABILIFY is also used to treat symptoms of depression in adults when administered with your current antidepressant medicine. It is prescribed when you do not respond adequately to an antidepressant alone and after you have tried different antidepressant treatments during your current depressive episode.

Some of the common symptoms of depression may include:

- feeling sad or hopeless
- loss of interest and enjoyment
- a change in appetite or weight
- difficulty concentrating or sleeping
- feeling tired
- headaches
- unexplained aches and pain

ABILIFY is not a cure, but it can help manage your symptoms and in adult patients may reduce the risk of relapse.

### **How does ABILIFY work?**

Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). Illnesses that affect the brain may be due to certain chemicals (dopamine and serotonin) in the brain being out of balance. These imbalances may cause some of the symptoms you may be experiencing. Exactly how ABILIFY works is unknown. However, it seems to correct the balance of these chemicals.

### **What are the ingredients in ABILIFY?**

Medicinal ingredient: aripiprazole

Non-medicinal ingredients: cornstarch, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. Coloring agents: 2 mg: FD&C Blue No. 2 Aluminum Lake and iron oxide yellow; 5 mg: FD&C Blue No. 2 Aluminum Lake; 10 mg and 30 mg: iron oxide red; 15 mg: iron oxide yellow.

### **ABILIFY comes in the following dosage forms:**

Tablets; 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg.

### **Do not use ABILIFY if:**

- You are allergic to aripiprazole or to any of the ingredients in ABILIFY (see list of Non-medicinal ingredients). ABILIFY contains lactose.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ABILIFY. Talk about any health conditions or problems you may have, including if you:**

- have or have a family history of diabetes or high blood sugar. Your doctor should check your blood sugar before you start taking ABILIFY and during your treatment.
- have or have had blackouts or seizures (convulsions).
- have or have had high blood pressure.
- suffer from high blood pressure or have rapid heart-beat and a drop in blood pressure when getting up.
- have a history of:
  - stroke
  - mini-stroke
  - high blood pressure

**Medicines like ABILIFY can raise the risk of stroke/mini-stroke in elderly people who have dementia.**

- have or have a family history of:
  - heart problems

- a condition called “congenital long QT syndrome” or “acquired long QT syndrome”
- any problems with the way your heart beats
- heart disease
- are taking any medication that affects how your heart beats.
- are an elderly patient and suffer from dementia (loss of memory and other mental abilities).
- are at risk for developing blood clots. Risk factors include:
  - having a family history of blood clots
  - being over the age of 65
  - smoking
  - being overweight
  - having a recent major surgery (such as hip or knee replacement)
  - not being able to move due to air travel or other reasons
  - taking oral birth control (“The Pill”)
- have or have had a low white blood cell count.
- have or have had involuntary, irregular muscle movements, especially in the face (tardive dyskinesia).
- drink alcoholic beverages or use recreational drugs
- have a history of drug abuse or addiction.
- have a history of gambling or impulse-control disorders (urge to gamble, spend money, eat or other urges).
- have a history of or are at risk of sleep apnea (a sleep disorder where your breathing is interrupted during sleep).
- have been told you are a “CYP2D6 poor metabolizer”.
- suffer from lactose intolerance or have one of the following rare hereditary diseases because lactose is a non-medicinal ingredient in ABILIFY:
  - Galactose intolerance
  - Glucose-galactose malabsorption
- are pregnant, think you are pregnant or plan to become pregnant. It is not known if ABILIFY may harm your unborn baby.
- are breastfeeding or plan to breastfeed. ABILIFY can pass into your milk and harm your baby. Talk to your healthcare professional about the best way to feed your baby if you take ABILIFY.

**Other warnings you should know about:**

**Self-harm:** If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital **right away**. You may find it helpful to tell a relative or close friend that you are depressed or have other mental illnesses. Ask them to read this leaflet. You might ask them to tell you if they:

- think your depression or mental illness is getting worse, or
- are worried about changes in your behaviour

**Impulse Behaviours:** The following behaviours may occur in some people who take ABILIFY:

- hypersexuality (uncontrollable and/or inappropriate sexual behaviour)
- an urge to gamble, spend money, binge eat, other urges or the development of new or increased urge

Tell your doctor **right away** if you or those close to you notice these behaviours.

**Complex Sleep-Related Behaviours:** While taking medicines such as ABILIFY, you may get out of bed while not being fully awake and do activities that you do not know you are doing, such as:

- sleep-walking
- eating

The next morning you may not remember that what you did during the night.

**Effects in Newborns:** In some cases, babies born to a mother taking ABILIFY during pregnancy have symptoms that are severe that require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. You should be ready to get emergency medical help for your newborn, if he/she:

- has trouble breathing
- is overly sleepy
- has muscle stiffness or floppy muscles (like a rag doll)
- is shaking or
- is having trouble feeding

**Falls:** The following symptoms have been reported with the use of antipsychotic drugs:

- feeling sleepy,
- a fall in blood pressure when you stand up from sitting or lying down,
- vision or speech problems

This can lead to falls that may cause fractures or other fall-related injuries. Certain medications, diseases or conditions can make this worse.

**Severe Skin Reactions:** In very rare cases, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with ABILIFY. Other skin reactions such as Stevens - Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Acute Generalized Exanthematous Pustulosis (AGEP) that can be serious or life-threatening have been reported in very rare cases with atypical antipsychotics.

These skin reactions can spread to your mouth, lips, face, hands, trunk (torso), arms and legs. Talk to your healthcare professional **right away** if you experience:

- fever
- severe rash
- peeling skin
- swelling of the face
- swollen lymph glands
- flu-like feeling
- yellow skin or eyes
- shortness of breath
- swelling of the legs
- dry cough
- chest pain or discomfort
- feeling thirsty
- urinating less often, less urine or dark urine

**Dehydration and Overheating:** It is important not to become too hot or dehydrated while you are taking ABILIFY.

- Do not exercise too much
- In hot weather, stay inside in a cool place if possible
- Stay out of the sun
- Do not wear too much clothing or heavy clothing

- Drink plenty of water.

**Neuroleptic Malignant Syndrome (NMS):** NMS is potentially a life-threatening condition that has been reported with the use of antipsychotic drugs like ABILIFY. Symptoms include:

- severe muscle stiffness or inflexibility with high fever,
- rapid or irregular heartbeat,
- sweating,
- state of confusion or reduced consciousness

**Weight Gain:** Your doctor should check your body weight before starting ABILIFY. They should continue to monitor it for as long as you are being treated with ABILIFY.

**Driving and Using Machines:** You should avoid driving a car or using machinery until you know how ABILIFY affects you. Some people experience:

- a change (reduced) judgment, thinking and motor skills
- feeling sleepy
- feeling light-headed (especially when going from sitting to standing) and
- possible fainting

**Blood Tests:** Your doctor should do blood tests before starting treatment with ABILIFY and while you are taking it. These tests will monitor:

- blood sugar
- cholesterol
- triglycerides and
- white blood cell count.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with ABILIFY:**

- ketoconazole or itraconazole, used to treat fungal infections
- quinidine, used to treat abnormal heartbeats
- paroxetine or fluoxetine, used to treat depression
- carbamazepine, used to treat seizures
- medicines used to lower your blood pressure
- alcohol. The effects of alcohol can be made worse if you drink alcohol while taking ABILIFY. **Do NOT** drink alcohol while taking ABILIFY.

While on ABILIFY, only take other medicines if your doctor tells you to.

**How to take ABILIFY:**

- Take ABILIFY exactly as your healthcare professional tells you to take it.
- Your doctor has decided on the best dosage for you based on your individual situation, but may change your dose depending on how you respond.
- Even if you feel better, do NOT change your dose or stop taking ABILIFY without speaking to your healthcare professional.
- ABILIFY can be taken with or without food. Always take the tablet with water and swallow it whole.
- Try to take ABILIFY at the same time each day.

**Usual dose:**  
**Schizophrenia**

**Usual adult dose:** 10 mg or 15 mg once a day. However, your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

**Usual adolescent (15 -17 years of age) dose:** 10 mg once a day. At the start of treatment, your doctor will prescribe a lower daily dose (2 mg) and will increase the dose to 5 mg once a day after 2 days and to the target dose of 10 mg once a day after 2 additional days. Depending on how well you respond and tolerate the 10 mg dose, your doctor may prescribe a lower or higher dose, to a maximum of 30 mg once a day.

**Manic or Mixed Episodes in Bipolar I Disorder**

**Usual adult dose:** 15 mg once a day. However, your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

**Usual adolescent (13 -17 years of age) dose:** 10 mg once a day. At the start of treatment, your doctor may prescribe a lower daily dose (2 mg once a day) and may increase the dose to 5 mg once a day after 2 days and to the target dose of 10 mg once a day after at least 2 additional days. Depending on how well you respond and tolerate the 10 mg dose, your doctor may prescribe a lower or higher dose, to a maximum of 30 mg once a day.

**Depression:**

**Usual adult dose:** 2 - 5 mg once a day administered with the antidepressant you are already taking. Depending on how well you respond and tolerate the initial dose, your doctor may prescribe a lower or higher dose, to a maximum of 15 mg once a day.

ABILIFY is not for use in children under 13 years of age for the treatment of manic or mixed episodes in bipolar I disorder, or for use in children under the age of 15 years for the treatment of schizophrenia.

**Overdose:**

If you think you have taken too much ABILIFY, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.
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**Missed Dose:**

If you miss a dose, take the missed dose as soon as you remember. If most of the day has passed, wait until your next scheduled dose. **Do not take two doses at the same time.**

**What are possible side effects from using ABILIFY?**

These are not all the possible side effects you may feel when taking ABILIFY. If you experience any side effects not listed here, contact your healthcare professional.

You should tell the doctor if you notice any symptoms that worry you, even if you think it is not connected with the medicine. **If any of these effects are severe, tell the doctor, nurse or pharmacist.**

Side effects may include:

- insomnia

- changes in weight (gain or loss)
- feeling restless
- headache
- anxiety
- drowsiness
- diarrhea, nausea and vomiting
- constipation
- an urge to gamble, to spend money, to eat (binge eating) or other urges (development of a new or increased urge)
- hypersexuality (uncontrollable and/or inappropriate sexual behaviour of severity or duration that causes distress)
- shaking (tremors)
- abnormal movements
- dizziness
- sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
- sleep walking and eating while asleep (sleep-related eating disorders)

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b> Skin Rash on its own	<b>X</b>		
Constipation	<b>X</b>		
<b>UNCOMMON</b> <b>Allergic Reaction:</b> Difficulty swallowing or breathing, wheezing; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat			<b>X</b>
<b>Tardive Dyskinesia:</b> Muscle twitching or unusual/abnormal movement of your face or tongue or other parts of your body		<b>X</b>	
<b>Stroke and Transient Ischemic Attacks:</b> Sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body; sudden confusion, difficulty speaking or understanding others; sudden difficulty in walking or loss of balance or coordination; suddenly feeling dizzy or sudden severe headache with no known cause			<b>X</b>

<b>Seizure (fits):</b> Loss of consciousness with uncontrollable shaking			<b>X</b>
<b>Restless Legs Syndrome:</b> unpleasant sensations in the legs; uncontrollable urge to move your legs that typically occurs in evening or during the night when sitting or lying down		<b>X</b>	
<b>Neuroleptic Malignant Syndrome:</b> Severe muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			<b>X</b>
<b>Priapism:</b> Long-lasting (greater than 4 hours in duration) and painful erection of the penis			<b>X</b>
<b>Blood Clots:</b> Swelling, pain and redness in an arm or leg that is warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations		<b>X</b>	
<b>Hyperglycemia</b> (high blood sugar): Increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue	<b>X</b>		
<b>Leukopenia</b> (decreased white blood cells): Infections, fatigue, fever, aches, pains, and flu-like symptoms		<b>X</b>	
<b>Hypotension</b> (low blood pressure): Dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up).	<b>X</b>		



<b>Severe Skin Reactions:</b> Fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine			<b>X</b>
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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store ABILIFY at room temperature (15°C - 30°C). Do not use ABILIFY after the expiry date which is stated on the label or carton after EXP.

Keep out of the reach and sight of children.

### If you want more information about ABILIFY:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.otsukacanada.com](http://www.otsukacanada.com)), or by calling 1-877-341-9245.

This leaflet was prepared by Otsuka Pharmaceutical Co., Ltd.

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