

PART III: CONSUMER INFORMATION

ABILIFY® Aripiprazole Tablets

This leaflet is part III of a three-part "Product Monograph" published when ABILIFY was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ABILIFY. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ABILIFY is used to treat symptoms of schizophrenia in adults and in adolescents (15-17 years of age). Schizophrenia is characterised by symptoms such as:

- hearing, seeing or sensing things that are not there
- suspiciousness, mistaken beliefs
- incoherent speech and behaviour and emotional flatness

People with this condition may also feel depressed, guilty, 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
- racing thoughts, easily losing train of thought
- overreaction to what is seen or heard
- misinterpretation of events
- sped-up activity, talking very quickly, too loudly, or more than usual
- decreased need for sleep
- poor judgment
- sometimes exhibiting 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.

Depression is a condition with symptoms such as:

- feeling sad
- a change in appetite or weight
- difficulty concentrating or sleeping
- feeling tired
- headaches
- unexplained aches and pain

It is important to discuss your depressive symptoms and possible side effects of ABILIFY with your doctor.

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

Your doctor may have prescribed ABILIFY for another reason. Ask your doctor if you have any questions about why ABILIFY has been prescribed for you.

What it does:

ABILIFY belongs to a group of medicines called atypical antipsychotic drugs.

Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). Illnesses that affect the brain may be due to certain chemicals in the brain being out of balance. These imbalances may cause some of the symptoms you may be experiencing. Doctors and scientists are not sure what causes these imbalances to occur. Exactly how ABILIFY works is unknown. However, it seems to adjust the balance of chemicals called dopamine and serotonin.

When it should not be used:

Do not take ABILIFY if you have had an allergic reaction to ABILIFY or any of the ingredients listed in the "What the nonmedicinal ingredients are" section of this leaflet. Signs of allergic reaction may include a rash, itching, shortness of breath or swelling of the face, lips or tongue.

What the medicinal ingredient is:

ABILIFY tablets contain the active ingredient called aripiprazole.

What the nonmedicinal ingredients are:

ABILIFY tablets contain the following inactive ingredients: lactose monohydrate, maize starch, microcrystalline cellulose, hydroxypropyl cellulose, magnesium stearate and 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).

What dosage forms it comes in:

ABILIFY tablets are available in strengths of 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Various medicines of the group to which ABILIFY belongs, including ABILIFY, have been associated with an increased rate of death when used in elderly patients with dementia. ABILIFY is not indicated in elderly patients with dementia.

ABILIFY is not for use in children with bipolar I disorder under 13 years of age or children with schizophrenia under the age of 15.

BEFORE you use ABILIFY talk to your doctor or pharmacist if you:

- are taking any other medicines (prescriptions or over the counter medicines).
- are pregnant, think you are pregnant or plan to become pregnant. You should not take ABILIFY if you are pregnant unless you have discussed this with your doctor.
- are breast-feeding or plan to breast-feed. Breast-feeding mothers should not take ABILIFY.
- have high blood sugar or a family history of diabetes.
- have a low white blood cell count.
- have ever had blackouts or seizures.
- have involuntary, irregular muscle movements, especially in the face.
- suffer from heart disease or have a family history of heart disease, stroke or "mini" stroke.
- have a history of any problems with the way your heart beats or if you are taking any medicines that may have an impact on the way your heart beats.
- suffer from abnormal (high) blood pressure or have rapid heart beat and a drop in blood pressure when getting up.
- are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.
- have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reason, take oral contraceptives ("The Pill").
- exercise vigorously or work in hot, sunny places.
- drink alcoholic beverages or use recreational drugs.
- have ever abused drugs.
- 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)
- suffer from lactose intolerance or have hereditary galactose intolerance or glucose-galactose malabsorption, because ABILIFY tablets contain lactose.

Thoughts of suicide and worsening of your depression or other mental illnesses:

If you are depressed and/or have other mental illnesses you may sometimes have thoughts of harming or killing yourself. These may be increased when first starting treatment, since these medicines all take time to work, usually about two weeks but sometimes longer.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or close friend that you are depressed or have other mental illnesses, and 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 if they are worried about changes in your behaviour.

Effects on newborns

In some cases, babies born to a mother taking ABILIFY during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek emergency medical attention for your newborn, if he/she has difficulty breathing, is overly sleepy, has muscle stiffness or floppy muscles (like a rag doll), is shaking or is having difficulty feeding.

INTERACTIONS WITH THIS MEDICATION

Tell all doctors, dentists and pharmacists who are treating you that you are taking ABILIFY.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- If you are taking other medicines, your doctor may need to change your dose of ABILIFY. You should tell your doctor if you are taking ketoconazole (antifungal), quinidine (antiarrhythmic), paroxetine (antidepressant) or fluoxetine (antidepressant). These medicines may lead to higher concentrations of aripiprazole in your blood.
- You should also tell your doctor if you are taking carbamazepine as it may lead to lower concentrations of aripiprazole in your blood, making ABILIFY less effective.

ABILIFY may increase the effect of medicines used to lower the blood pressure. Be sure to tell your doctor if you take a medicine to keep your blood pressure under control.

The effects of alcohol could be made worse while taking ABILIFY. It is recommended that you **do not** drink alcohol while taking ABILIFY.

Only take other medicines while you are on ABILIFY if your doctor tells you to.

PROPER USE OF THIS MEDICATION

The most important thing about taking ABILIFY is to take it exactly the way your doctor has prescribed it, every day. You should check with your doctor or pharmacist if you are not sure. Your doctor has decided on the best dosage for you based on your individual situation. Your doctor may increase or decrease your dose depending on your response.

Schizophrenia

Usual adult dose: The usual dose is 10 mg or 15 mg once a day, without regard to meals. 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: The usual dose is 10 mg once a day, without regard to meals. 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: The usual dose is 15 mg once a day, without regard to meals. However, your doctor may increase the dose to 30 mg once a day.

Usual adolescent (13 -17 years of age) dose:

The usual dose is 10 mg once a day, without regard to meals. 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.

The maximum dose should not exceed 30 mg once a day

Depression:

Usual adult dose: The usual starting dose is 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.

Try to take ABILIFY at the same time each day. It does not matter whether you take it with or without food. Always take the tablet with water and swallow it whole.

If you have the impression that the effect of ABILIFY is too strong or too weak, talk to your doctor or pharmacist.

Even if you feel better, do not change or discontinue the daily dose of ABILIFY without first consulting your doctor. Although ABILIFY cannot cure your condition, it can help relieve your symptoms. If your symptoms improve or disappear, it is probably because your treatment is working. ABILIFY should be taken for as long as you and your doctor believe it is helping you.

Do not give ABILIFY to anyone else. Your doctor has prescribed it for you and your condition.

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 have taken more ABILIFY tablets than your doctor has prescribed (or if someone else has taken some of your ABILIFY tablets), contact your regional Poison Control Centre and talk to your doctor right away or go to your nearest hospital emergency department. Take the medication package with you.

Missed Dose:

If you miss a dose, take the missed dose as soon as you remember but **do not take two doses in one day.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medicines, ABILIFY can cause some side effects. These side effects are most likely to be minor and temporary. However, some may be serious and need medical attention.

Certain side effects occur more frequently in adolescent compared to adult patients, including abnormal movements, drowsiness and weight gain.

The most common side effects of ABILIFY are:

- feeling of restlessness (akathisia)
- drowsiness
- shaking (tremors)
- abnormal movements
- nausea, vomiting, upset stomach
- dizziness
- constipation
- headaches
- insomnia
- anxiety
- sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
- sleep walking and eating while asleep (sleep-related eating disorders)

The following other side effects may also happen in some people who take ABILIFY:

- weight gain
- increase in the amount of sugar (glucose) in the blood (hyperglycemia). Symptoms of high blood sugar can include feeling very thirsty and/or hungry, needing to urinate more than usual, feeling weak or tired, feeling sick to your stomach, feeling confused, fruity smelling breath.
- decrease in the amount of white blood cells.

- difficulty swallowing, which may lead to aspiration and choking.
- decreased blood pressure. Symptoms of decreased blood pressure can include lightheadedness or fainting when rising too quickly from a sitting or lying position.
- hypersexuality (uncontrollable and/or inappropriate sexual behaviour of severity or duration that causes distress).
- an urge to gamble, to spend money, to eat (binge eating) or other urges (development of a new or increased urge).

Because some people experience sleepiness, you should avoid driving a car or operating machinery until you know how ABILIFY affects you.

Your doctor should check your body weight before starting ABILIFY and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting ABILIFY. These tests will monitor blood sugar, cholesterol, triglycerides and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

You should tell your doctor if you notice any symptoms that worry you, even if you think the problems are not connected with the medicine or are not listed here.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
	Only if severe	In all cases	
Seizure: Loss of consciousness with uncontrollable shaking			x
Neuroleptic Malignant Syndrome: Pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			x
Priapism: Long-lasting (greater than 4 hours in duration) and painful erection of the penis			x
Blood Clots: 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		x	

This is not a complete list of side effects. For any unexpected effects while taking ABILIFY, contact your doctor or pharmacist.

HOW TO STORE IT

ABILIFY should be stored at room temperature (15°C - 30°). 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.

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/adverse-reaction-reporting.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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
	Only if severe	In all cases	
Common			
Skin Rash on its own	x		
Constipation	x		
Uncommon			
Tardive Dyskinesia: Muscle twitching or abnormal movement of your face or tongue		x	
Stroke and Transient Ischemic Attacks: Sudden weakness or numbness of the face, arms, or legs and speech or vision problems			x
Allergic Reaction: Symptoms include swelling in the mouth, tongue, face and throat, itching, rash.			x

MORE INFORMATION

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 Consumer Information by visiting the Health Canada website (www.healthcanada.gc.ca); the manufacturer's website (www.otsukacanada.com), or by calling 1-877-341-9245.

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

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