

**PART III: CONSUMER INFORMATION****Pr ARIPIPRAZOLE****Aripiprazole Tablets, House Standard**

2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg

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

**ABOUT THIS MEDICATION****What the medication is used for:**

ARIPIPRAZOLE 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.

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

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

**What it does:****ARIPIPRAZOLE 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 ARIPIPRAZOLE 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 ARIPIPRAZOLE if you have had an allergic reaction to ARIPIPRAZOLE 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:**

Aripiprazole.

**What the nonmedicinal ingredients are:**

Croscarmellose Sodium, Hydroxypropyl-Cellulose, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose. In addition, the following strengths contain:

- 2 mg: indigo carmine, iron oxide yellow.
- 5 mg: indigo carmine.
- 10 mg: iron oxide red.
- 15 mg: iron oxide yellow.
- 30 mg: iron oxide red.

**What dosage forms it comes in:**

**Tablets:** 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 ARIPIPRAZOLE belongs, including ARIPIPRAZOLE, have been associated with an increased rate of death when used in elderly patients with dementia. ARIPIPRAZOLE is not indicated in elderly patients with dementia.

ARIPIPRAZOLE is not for use in children with schizophrenia under the age of 15.

**BEFORE you use ARIPIPRAZOLE 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 ARIPIPRAZOLE 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 ARIPIPRAZOLE.
- 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 heartbeat 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 ARIPIPRAZOLE 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 aripiprazole 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 ARIPIPRAZOLE.

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 ARIPIPRAZOLE. 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 ARIPIPRAZOLE less effective.

ARIPIPRAZOLE 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 ARIPIPRAZOLE. It is recommended that you **do not** drink alcohol while taking ARIPIPRAZOLE.

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

**PROPER USE OF THIS MEDICATION**

The most important thing about taking ARIPIPRAZOLE 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 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.

The maximum dose should not exceed 30 mg once a day.

Try to take ARIPIPRAZOLE 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 ARIPIPRAZOLE 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 ARIPIPRAZOLE without first consulting your doctor. Although ARIPIPRAZOLE cannot cure your condition, it can help relieve your symptoms. If your symptoms improve or disappear, it is probably because your treatment is working. ARIPIPRAZOLE should be taken for as long as you and your doctor believe it is helping you.

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

ARIPIPRAZOLE is not for use in children under the age of 15 years for the treatment of schizophrenia.

**Overdose:**

If you have taken more ARIPIPRAZOLE tablets than your doctor has prescribed (or if someone else has taken some of your ARIPIPRAZOLE 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, ARIPIPRAZOLE 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 ARIPIPRAZOLE 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 ARIPIPRAZOLE:

- 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 ARIPIPRAZOLE affects you.

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

Your doctor should take blood tests before starting ARIPIPRAZOLE. 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 medical attention
	Only if severe	In all cases	
<b>Common</b>			
<b>Skin Rash on its own</b>	✓		
<b>Constipation</b>	✓		
<b>Uncommon</b>			
<b>Tardive Dyskinesia:</b> Muscle twitching or abnormal movement of your face or tongue		✓	
<b>Stroke and Transient Ischemic Attacks:</b> Sudden weakness or numbness of the face, arms, or legs and speech or vision problems			✓
<b>Allergic Reaction:</b> Symptoms include swelling in the mouth, tongue, face and throat, itching, rash			✓
<b>Seizure:</b> Loss of consciousness with uncontrollable shaking			✓
<b>Neuroleptic Malignant Syndrome:</b> Pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			✓

**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 medical attention
	Only if severe	In all cases	
<b>Priapism:</b> Long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
<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		✓	

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

**HOW TO STORE IT**

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

Do not use ARIPIPRAZOLE after the expiry date which is stated on the label 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.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.*

**MORE INFORMATION**

If you want more information about ARIPIPRAZOLE:

- 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>), or by contacting Pro Doc Ltée at 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca) or [info@prodoc.qc.ca](mailto:info@prodoc.qc.ca).

This leaflet was prepared by

**Pro Doc Ltée**

Laval, Québec

H7L 3W9

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