

PART III: CONSUMER INFORMATION

Pr ABILIFY MAINTENA®

Aripiprazole for prolonged release injectable suspension

Read this carefully before you start taking ABILIFY MAINTENA and each time you get a refill. This leaflet is a summary and will not tell you everything about ABILIFY MAINTENA. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about ABILIFY MAINTENA.

ABOUT THIS MEDICATION

What the medication is used for:

ABILIFY MAINTENA is used for the treatment of schizophrenia in adults. Schizophrenia is characterized by symptoms such as:

- hallucinations; hearing, seeing or sensing things that are not there,
- suspiciousness, mistaken beliefs,
- incoherent speech and behavior and emotional flatness.

People with this condition may also feel depressed, guilty, anxious or tense.

ABILIFY MAINTENA is also used to treat adults who suffer from 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.

What it does:

ABILIFY MAINTENA 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 MAINTENA works is unknown. However, it seems to adjust the balance of chemicals called dopamine and serotonin.

You and your doctor have decided on ABILIFY MAINTENA to help relieve the symptoms that are

bothering you or the patient you are caring for. Although ABILIFY MAINTENA cannot cure the illness, it can improve the symptoms and keep them under control, reducing the risk of relapse as you or the patient you're caring for continue(s) treatment.

When it should not be used:

Do not use ABILIFY MAINTENA if you or the patient you are caring for:

- are allergic to aripiprazole or any of the ingredients listed in the "What the non-medicinal ingredients are" section of the leaflet.

What the medicinal ingredient is:

Aripiprazole

What the non-medicinal ingredients are:

Carboxymethyl cellulose sodium, mannitol, sodium phosphate monobasic monohydrate and sodium hydroxide.

What dosage forms it comes in:

300mg and 400mg vial

300mg and 400 mg Dual Chamber Syringe

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

BEFORE you or the patient you are caring for uses ABILIFY MAINTENA talk to your/their doctor, nurse or pharmacist if you/they:

- have never taken ABILIFY® (aripiprazole) tablets before.
- have diabetes or high blood sugar or a family history of diabetes or high blood sugar. Your healthcare provider should check your blood sugar before you start receiving ABILIFY MAINTENA and during your treatment.
- have or had blackouts or seizures (convulsions).
- 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 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 care giver/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").

- have or had low white blood cell count.
- 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 condition called "congenital long QT syndrome" or "acquired long QT syndrome".
- 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).
- have any other medical problems including problems that may affect you receiving an injection in your arm or buttocks.
- are less than 18 years old or older than 65 years of age.
- are pregnant, think you are pregnant or plan to become pregnant. It is not known if ABILIFY MAINTENA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. ABILIFY MAINTENA can pass into your milk and harm your baby. Talk to your healthcare provider about the best way to feed your baby if you or the patient you are caring for receive ABILIFY MAINTENA.

Self-harm: 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 MAINTENA 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.

Falls: Feeling sleepy, a fall in blood pressure when you stand up from sitting or lying down, vision and speech problems have been reported with the use of antipsychotic drugs. This can lead to falls that may cause fractures or other fall related-injuries. Certain medications, diseases or conditions can make this worse.

Driving and using machines: Because some people experience impaired judgment, thinking and motor skills, sleepiness, lightheadedness (especially when going from sitting to standing) and possible fainting, you or the patient you are

caring for should avoid driving a car or operating machinery until you know how ABILIFY MAINTENA affects you/the patient you are caring for.

INTERACTIONS WITH THIS MEDICATION

Tell all doctors, dentists, nurses and pharmacists who are treating you or the patient that you are caring for that you/they are taking ABILIFY MAINTENA.

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you, or the patient you are caring for take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

If you or the patient you are caring for are taking other medicines, your/their doctor may need to change the dose of ABILIFY MAINTENA.

The following may interact with ABILIFY MAINTENA:

- ketoconazole (antifungal), quinidine (antiarrhythmic), paroxetine (antidepressant) or fluoxetine (antidepressant). These medicines may lead to higher concentrations of aripiprazole in your blood.
- carbamazepine. It may lead to lower concentrations of aripiprazole in your blood, making ABILIFY MAINTENA less effective.
- drugs used to lower blood pressure. ABILIFY MAINTENA may increase the effect of medicines used to lower the blood pressure.

The effects of alcohol could be made worse while taking ABILIFY MAINTENA. It is recommended that you or the patient you are caring for **do not** drink alcohol while taking ABILIFY MAINTENA.

Only take other medicines while you, or the patient you are caring for are on ABILIFY MAINTENA if your/their doctor tells you/them to.

PROPER USE OF THIS MEDICATION

ABILIFY MAINTENA is a long-acting medicine that a Healthcare Professional will give to you or the patient that you are caring for by injection. This means you or the patient do not have to take this medicine every day as it is designed to deliver the right amount of medication to provide sustained control for a whole month after each injection.

You or the patient you are caring for will only need to get a dose once a month.

Schizophrenia and Bipolar Disorder

Usual adult dose: The usual dose is 400 mg, once monthly, administered as a single injection in the arm or buttock by a Healthcare Professional.

You or the patient you are caring for may feel a little pain in the arm or buttock during the injection.

After the first ABILIFY MAINTENA injection, treatment should be continued with 10 mg to 20 mg oral aripiprazole (or other oral antipsychotic) for 14 days in a row to keep the right concentration of antipsychotic medicine in your/the patient you are caring for blood while switching to getting your/their medicine by injection.

Overdose:

If you think you have taken too much ABILIFY MAINTENA, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

You/the patient you are caring for should not miss a dose of ABILIFY MAINTENA. If a dose is missed for some reason, call your/their Healthcare Provider right away to let him or her know you or the patient you are caring for missed the injection and ask what you or the patient you are caring for should do next.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- insomnia
- changes in weight (gain or loss)
- feeling of restlessness
- headache
- anxiety
- the common cold
- pain at the injection site
- drowsiness
- diarrhea, nausea and vomiting
- 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
- increased fat levels (cholesterol and triglycerides) in your blood
- hiccups
- problems with speech
- excessive sweating
- hair loss
- increased liver enzyme levels in your blood
- inflammation of the liver
- loss of consciousness and violent muscle contractions (grand mal convulsion)

- sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
- sleep walking and eating while asleep (sleep-related eating disorders)

If any of these affects you severely, tell your doctor, nurse or pharmacist.

Do not drink alcohol while on ABILIFY MAINTENA treatment.

Do not become too hot or dehydrated while you receive ABILIFY MAINTENA.

- 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.

The doctor should check body weight before starting ABILIFY MAINTENA and continue to monitor it for as long as you or the patient you are caring for are being treated.

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

You should tell your doctor if you notice any symptoms that worry you or the patient you are caring for, 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, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	Skin Rash	√		
	Constipation	√		
Uncommon	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

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

Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Uncommon Tardive Dyskinesia: muscle twitching or unusual movement of the face or tongue		√	
			√
Uncommon Stroke and Transient Ischemic Attacks: Sudden weakness or numbness of the face, arms, or legs and speech or vision problems			√
			√
		√	
Uncommon Seizure: Loss of consciousness with uncontrollable shaking			√
			√
Uncommon 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		√	
			√
Uncommon Neuroleptic Malignant Syndrome: Pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			√
	√		
Increased blood sugar: frequent urination, thirst, and hunger	√		

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

Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√	
Dystonia: tightness of the throat, difficulty swallowing or breathing which may lead to choking		√	
Low Blood Pressure: dizziness, fainting, light-headedness May occur when you go from lying or sitting to standing up.	√		

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

HOW TO STORE IT

Dual chamber syringe:
Store between 15 and 30°C. Do not freeze. Protect the syringe from light by storing in the original package until time of use.

Vial:
ABILIFY MAINTENA should be stored between 15 and 30°C.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
Fax toll-free to 1-866-678-6789, or
Mail to: Canada Vigilance Program
 Health Canada
 Postal Locator 1908C
 Ottawa, Ontario
 K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Otsuka Pharmaceutical Co., Ltd., at: 1-877-341-9245.

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

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