

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

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 this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ABILIFY MAINTENA**.

Serious Warnings and Precautions

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

What is ABILIFY MAINTENA used for?

ABILIFY MAINTENA is used for the treatment of schizophrenia in adults. 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 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
- 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

How does ABILIFY MAINTENA 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 MAINTENA works is unknown. However, it seems to correct the balance of these chemicals.

What are the ingredients in ABILIFY MAINTENA?

Medicinal ingredients: aripiprazole

Non-medicinal ingredients: carboxymethyl cellulose sodium, mannitol, sodium hydroxide and sodium phosphate monobasic monohydrate.

ABILIFY MAINTENA comes in the following dosage forms:

Powder for suspension: 300 mg and 400 mg

ABILIFY MAINTENA comes in 2 types of kits:

- single-use pre-filled dual chamber syringe
- single-use vial

Do not use ABILIFY MAINTENA if:

- You / the person you are caring for are allergic to aripiprazole or to any of the ingredients in ABILIFY MAINTENA (see list of Non-medicinal ingredients).

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

- have never taken ABILIFY® (aripiprazole) tablets before.
- have diabetes or high blood sugar or a family history of diabetes or high blood sugar. Your doctor 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:
 - stroke
 - mini stroke. You or your care giver/relative should tell your doctor if you have ever had a stroke or mini stroke

Medicines like ABILIFY MAINTENA 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.
- suffer from high blood pressure or have rapid heart-beat and a drop in blood pressure when getting up.
- 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 had 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 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 from 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.

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

Complex sleep-related behaviours: While taking medicines such as ABILIFY MAINTENA, 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.

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

- 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.

Effects on newborns: In some cases, babies born to a mother taking ABILIFY MAINTENA 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 MAINTENA. 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.

This skin reaction can spread to your mouth, lips, face, hands, trunk (torso), arms and legs. Contact your healthcare professional **right away** if you/the patient you are caring for experiences any of the following symptoms at any time during treatment with ABILIFY MAINTENA:

- fever
- severe rash
- blisters or 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 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.

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

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

Weight Gain: The doctor should check body weight before starting ABILIFY MAINTENA. They should continue to monitor it for as long as you/the patient you/is taking ABILIFY MAINTENA.

Driving and Using Machines: You or the patient you are caring for should avoid driving a car or using machinery until you know how ABILIFY MAINTENA affects you/them. 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: The doctor should do blood tests before starting treatment with ABILIFY MAINTENA and while you or the patient you are caring for are taking it. These tests will monitor:

- blood sugar
- cholesterol
- triglycerides and
- white blood cells 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 MAINTENA:

- ketoconazole used to treat fungal infections
- quinidine used to treat abnormal heartbeats
- paroxetine or fluoxetine used to treat depression
- carbamazepine, phenytoin, phenobarbital or primidone used to treat seizures
- rifampicin used to treat tuberculosis
- rifabutin, efavirenz or nevirapine used to treat HIV
- medicines used to lower your blood pressure
- St. John's Wort
- Alcohol. The effects of alcohol can be made worse if you drink alcohol while taking ABILIFY MAINTENA. **Do NOT** drink alcohol while taking ABILIFY MAINTENA.

While on ABILIFY MAINTENA, only take/give other medicines if your doctor or the doctor for the patient you are caring tells you to.

How ABILIFY MAINTENA is given:

ABILIFY MAINTENA is a long-acting medicine. This means you/the patient you are caring for do not have to take it every day. It will be given to you **once a month** by a healthcare professional as an injection into the muscle on the upper part of your arm (deltoid) or in your buttocks.

There are 2 ways you can start treatment with ABILIFY MAINTENA. Your doctor will decide which way is right for you.

- **Starting with 1 injection:** you will need to continue taking your oral aripiprazole or your other oral antipsychotic everyday for 14 days starting on the day you get the first injection. This will keep the right amount of an antipsychotic medicine in your blood until your next injection. Your doctor will tell you how much of the oral antipsychotic to take for the 14 days.
- **Starting with 2 injections:** you will need to take only one dose of 20 mg oral

aripiprazole on the same day.

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

Usual adult dose: After the first ABILIFY MAINTENA injection, the usual dose is 400 mg, once a month.

Overdose:

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

Signs of an overdose include:

- an increase in your blood pressure
- feeling tired
- feeling sleepy
- an increase in you heart rate
- nausea
- vomiting
- diarrhea

Missed Dose:

You/the patient you are caring for should not miss a dose of ABILIFY MAINTENA.

If a dose is missed, call your doctor **right away** and ask what you should do next.

What are possible side effects from using ABILIFY MAINTENA?

These are not all the possible side effects you may feel when taking ABILIFY MAINTENA. 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/the patient you are caring for, even if you think it is not connected with the medicine. **If any of these affects are severe, tell the doctor, nurse or pharmacist.**

Side effects may include:

- insomnia
- changes in weight (gain or loss)
- feeling restless
- 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)
- 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)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Skin Rash	X		
Constipation	X		
UNCOMMON Allergic Reaction: difficulty swallowing or breathing, wheezing; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat			X
Tardive Dyskinesia: muscle twitching or unusual/abnormal movement of your face or tongue or other parts of your body		X	
Stroke and Transient Ischemic Attacks: 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.			X
Seizure (fits): loss of consciousness with uncontrollable shaking			X
Priapism: long-lasting (greater than 4 hours in duration) and			X

painful erection of the penis			
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	
Neuroleptic Malignant Syndrome: severe muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			X
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue	X		
Leukopenia (decreased white blood cells): infections, fatigue, fever, aches, pains, and flu-like symptoms		X	
Dystonia: twisting movements that you cannot control and can affect posture or the face including eyes, mouth, tongue or jaw, tightness of the throat, difficulty swallowing or breathing which may lead to choking		X	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up).	X		
Severe Skin Reactions: 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, swelling of face and/or legs, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine			X
Restless Leg Syndrome:	X		

uncontrollable urge to move your legs typically occurs in evening or during the night when sitting or lying down			
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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:

- 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: store between 15 and 30°C.

Keep out of reach and sight of children.

If you want more information about ABILIFY MAINTENA:

- 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, or by calling 1-877-341-9245.

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

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