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R_x **Aripiprazole**
Abilify Maintena[®]

GETTING STARTED WITH
ARIPIRAZOLE (ABILIFY MAINTENA[®])



A GUIDE FOR PATIENTS,
FAMILIES AND CARERS



Models in photos are used for illustrative purposes only.

What is Aripiprazole (Abilify Maintena)?

Aripiprazole (Abilify Maintena) is a long-acting antipsychotic medicine that is used to control the symptoms of schizophrenia.

Schizophrenia is characterized by symptoms such as:



Hallucinations; hearing, seeing or sensing things that are not there,



Suspiciousness, mistaken beliefs and



Incoherent speech and behaviour and emotional flatness

People with this condition may also feel depressed, guilty, anxious or tense. Aripiprazole (Abilify Maintena) is available only with your doctor's prescription.

Do not receive Aripiprazole (Abilify Maintena) if you are allergic to aripiprazole or any of the ingredients in Aripiprazole (Abilify Maintena). See the end of this Medication Guide for a complete list of ingredients in Aripiprazole (Abilify Maintena).

Before receiving Aripiprazole (Abilify Maintena), tell your healthcare provider about all your medical conditions, including if you:



have never taken aripiprazole 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 Aripiprazole (Abilify Maintena) and during your treatment.



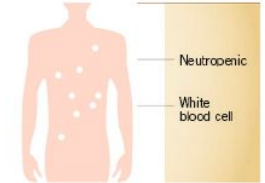
have or had seizures (convulsions)



have or had low or high blood pressure



have or had heart problems or a stroke



have or had a low white blood cell count



have problems that may affect you receiving an injection in your arm or buttocks



are pregnant or plan to become pregnant. It is not known if Aripiprazole (Abilify Maintena) will harm your unborn baby.



If you become pregnant while receiving Aripiprazole (Abilify Maintena), talk to your healthcare provider.



are breastfeeding or plan to breastfeed. Aripiprazole (Abilify Maintena) can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive Aripiprazole (Abilify Maintena).



have allergies to any other medicines, foods, preservatives or dyes.



have or have had any medical conditions

Tell your doctor about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Aripiprazole (Abilify Maintena) and other medicines may affect each other causing possible serious side effects. Aripiprazole (Abilify Maintena) may affect the way other medicines work, and other medicines may affect how Aripiprazole (Abilify Maintena) works.

Your doctor can tell you if it is safe to receive Aripiprazole (Abilify Maintena) with your other medicines. Do not start or stop any medicines during treatment with Aripiprazole (Abilify Maintena) without talking to your doctor first. Know the medicines you take. Keep a list of them to show your doctor when you get a new medicine.

How Should I Receive Aripiprazole (Abilify Maintena)?

- Follow your Aripiprazole (Abilify Maintena) treatment schedule exactly as your doctor tells you to.
- Aripiprazole (Abilify Maintena) is an injection given in your arm or buttock by your healthcare provider 1 time every month.** You may feel a little pain in your arm or buttock during your injection.
- After your first injection of Aripiprazole (Abilify Maintena) you should continue your current antipsychotic medicine for 2 weeks.
- You should not miss a dose of Aripiprazole (Abilify Maintena). If you miss a dose for some reason, call your doctor right away to discuss what you should do next.

What should I avoid while receiving Aripiprazole (Abilify Maintena)?



Do not drive, operate machinery, or do other dangerous activities until you know how Aripiprazole (Abilify Maintena) affects you.



Aripiprazole (Abilify Maintena) may make you feel drowsy.



Do not drink alcohol while you receive Aripiprazole (Abilify Maintena).



Do not become too hot or dehydrated while you receive Aripiprazole (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

What are the possible side effects of Aripiprazole (Abilify Maintena)?

Aripiprazole (Abilify Maintena) may cause serious side effects, including:

- Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.
- Neuroleptic malignant syndrome (NMS), a serious condition that can lead to death. Call your healthcare provider or go to the nearest emergency room right away if you have some or all of the following symptoms of NMS:



High fever



Stiff muscles



Confusion



Sweating



Change in pulse, heart rate, and blood pressure

- Uncontrolled body movements (tardive dyskinesia). Aripiprazole (Abilify Maintena) may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop receiving Aripiprazole (Abilify Maintena). Tardive dyskinesia may also start after you stop receiving Aripiprazole (Abilify Maintena).

- Problems with your metabolism such as: high blood sugar (hyperglycemia): Increases in blood sugar can happen in some people who receive Aripiprazole (Abilify Maintena). Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your healthcare provider should check your blood sugar before you start receiving Aripiprazole (Abilify Maintena) and during your treatment.

Call your healthcare provider if you have any of these symptoms of high blood sugar while receiving Aripiprazole (Abilify Maintena):



feel very thirsty



need to urinate more than usual



feel very hungry



feel weak or tired



feel sick to your stomach



feel confused, or your breath smells fruity

- Increased fat levels (cholesterol and triglycerides) in your blood.
- Weight gain. You and your healthcare provider should check your weight regularly.
- Unusual urges. Some people receiving Aripiprazole (Abilify Maintena) have had unusual urges such as gambling, binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges. If you or your family members notice that you are having unusual urges or behaviours, talk to your healthcare provider.
- Decreased blood pressure (orthostatic hypotension). You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.

- Low white blood cell count
- Seizures (convulsions)
- Problems controlling your body temperature so that you feel too warm. See *"What should I avoid while receiving Aripiprazole (Abilify Maintena)?"*
- Difficulty swallowing

The most common side effects of Aripiprazole (Abilify Maintena) include: weight gain, inner sense of restlessness such as feeling like you need to move (akathisia), injection site pain, or sleepiness (sedation). These are not all the possible side effects of Aripiprazole (Abilify Maintena).

Call your doctor for medical advice about side effects. You may report side effects at

(02) 888-6774

or email

oppi-pv@otsuka.com.ph

General information about the safe and effective use of Aripiprazole (Abilify Maintena). If you would like more information, talk with your doctor.

When you must not receive it?



EXPIRED

- Do not receive Aripiprazole (Abilify Maintena) if you have an allergy to:
 - Aripiprazole; or
 - Any of the ingredients listed at the end of this leaflet
 Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; and/or rash, itching or hives on the skin.
- Aripiprazole (Abilify Maintena) should not be used after the expiry date (EXP) printed on the pack.

How to use Aripiprazole (Abilify Maintena)?

Aripiprazole (Abilify Maintena) is a long-acting antipsychotic medicine that a healthcare professional will give to you by injection via muscle in your buttocks or muscle in your upper arm.

The medicine is slowly released from the injection site, which means you do not have to take it every day, but only once a month

Aripiprazole (Abilify Maintena) can be received regardless of meals.



The usual dose is **400mg every 4 weeks**. Your doctor may administer a lower dose if required. Your doctor will decide on the dose of Aripiprazole (Abilify Maintena) that is right for you

After your first dose you must take 10mg to 20mg of oral aripiprazole (or prescribed dose of other oral antipsychotic) for 14 days in a row

It is important you take your oral antipsychotic exactly as directed by your doctor, because the first injection will not start to work right away.

How many injections you will need?

Aripiprazole (Abilify Maintena) should be administered to you **once monthly** to help reduce your symptoms and the risk of relapse. **Do not stop treatment just because you feel better.** It is important that you carry on receiving Aripiprazole (Abilify Maintena) for as long as your doctor has told you to.

What if I miss the dose?

If you miss an injection, you should contact your doctor to arrange your next injection as soon as you can. You should be given an injection every 4 weeks. Ask your doctor if you have any further questions on the use of this medicine.

While you are receiving Aripiprazole (Abilify Maintena)?

Patients and caregivers should pay attention to any of the warning signs of suicide-related behaviour such as thoughts or talk about death or suicide; or thoughts or talk about self-harm or doing harm to others. Tell your doctor immediately if you have any of these signs.

Tell your doctor as soon as possible if you do not feel well while you are receiving Aripiprazole (Abilify Maintena). All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following side effects and they worry you:

- Headache
- Drowsiness
- Pain or swelling at the site of the injection
- Weight loss
- Shaking
- Fatigue
- Sleepiness
- Dry mouth
- Inability for a man to have an erection
- Inability to sit or stand still, restless movement of the arms and legs such as tapping, marching in places, rocking, crossing and uncrossing legs
- Depression
- Blurred vision



Tell your doctor as soon as possible if you notice any of the side effects listed below. These side effects may occur rarely.



Feeling dizzy or fainting, especially when getting up from a lying or sitting position



Frequent infections such as fever, severe chills, sore throat or mouth ulcers



Difficulty swallowing

