

Abilify Maintena®

Vial

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Abilify Maintena?

Abilify Maintena contains the active ingredient aripiprazole. Abilify Maintena is a long-acting medicine that is used to treat schizophrenia and Bipolar I Disorder. For more information, see Section [1. Why am I using Abilify Maintena?](#) in the full CMI.

2. What should I know before I use Abilify Maintena?

Abilify Maintena should only be given by a healthcare professional.

Do not receive if you have ever had an allergic reaction to aripiprazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Abilify Maintena?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Abilify Maintena and affect how it works. These include: medicines and herbal remedies used to treat depression and anxiety, certain medicines used to treat nicotine dependence, anticonvulsants used to treat epilepsy, medicines used to treat high blood pressure, medicines used to treat heart rhythm disturbances, medicines used to treat bacterial, fungal or viral infections. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Abilify Maintena?

Abilify Maintena is a long-acting medicine that a healthcare professional will give to you by injection. More instructions can be found in Section [4. How do I use Abilify Maintena?](#) in the full CMI.

5. What should I know while using Abilify Maintena?

Things you should do	<ul style="list-style-type: none">• Tell your doctor immediately if you become pregnant while taking Abilify Maintena.• Tell your doctor if you are about to be started on any new medicine• Tell your doctor if you are going to have surgery that requires a general anaesthetic
Things to be careful of	<ul style="list-style-type: none">• If Abilify Maintena makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Abilify Maintena affects you.
Drinking alcohol	<ul style="list-style-type: none">• Avoid alcohol while you are taking Abilify Maintena.

Looking after your medicine

- Abilify Maintena will be stored by your healthcare professional until it is time for them to administer the injection to you.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

Mild side effects include: Headache, fatigue, drowsiness or sleepiness, speech disorder, agitation or restlessness, inability to sit or stand still. **Serious side effects (Call your doctor straight away, or go straight to the Emergency Department)** include: serious allergic reaction (symptoms may include swelling of the face, lips, mouth or throat, or rash, itching or hives), abnormal movements of the tongue; high fever, stiff muscles, confusion, sweating, and changes in pulse, heart rate, and blood pressure; convulsions or seizures

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Abilify Maintena[®]

Active ingredient(s): *Aripiprazole (ari-pip-rah-zol)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Abilify Maintena. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Abilify Maintena.**

Where to find information in this leaflet:

- [1. Why am I using Abilify Maintena?](#)
- [2. What should I know before I use Abilify Maintena?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Abilify Maintena?](#)
- [5. What should I know while using Abilify Maintena?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Abilify Maintena?

Abilify Maintena contains the active ingredient aripiprazole. Abilify Maintena belongs to a group of medicines called antipsychotic agents. Abilify Maintena helps to correct a chemical imbalance in the brain which may cause schizophrenia and Bipolar I Disorder.

Abilify Maintena is a long-acting medicine that is used to treat schizophrenia and Bipolar I Disorder.

Schizophrenia is characterised 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.

Bipolar disorder is a condition with symptoms such as:

- feeling "high", having excessive amounts of energy,
- needing much less sleep than usual,
- talking very quickly with racing ideas and
- sometimes severe irritability.

You and your doctor have decided on Abilify Maintena to help relieve the symptoms of your condition. Although Abilify Maintena cannot cure your condition, it can help to keep the symptoms under control and reduce the risk of relapse as you continue treatment.

2. What should I know before I use Abilify Maintena?

Abilify Maintena should only be given by a healthcare professional.

Warnings

Do not receive Abilify Maintena if:

- you are allergic to aripiprazole, or any of the ingredients listed in 7. Product details at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you:

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

Have any other medical conditions especially the following conditions:

- Dementia (loss of memory or other mental abilities) and you are elderly.
- Neuroleptic malignant syndrome - reaction to some medicines with a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure, which may lead to coma.
- Tardive dyskinesia - a reaction to some medicines with abnormal movements of the tongue, or other

uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs.

- low blood pressure.
- high blood pressure or have rapid heartbeat and a drop in blood pressure when getting up.
- problems with your heart or blood vessels, including stroke, "mini" stroke, or family history of heart or blood vessel problems.
- epilepsy, seizures or fits.
- if you have any conditions or are taking medications that could increase the risk of falling, such as a drop in blood pressure when getting up, excess sleepiness.
- problems with your oesophagus (food pipe/gullet) such as difficulty in swallowing.
- high blood sugar or diabetes mellitus or a family history of diabetes or high blood sugar.
- blood clots, or you have any of the following risk factors for developing blood clots: family history of blood clots, 65 years of age or older, smoking, obese, recent major surgery such as hip or knee replacement, immobility due to air travel or other reason, or you take oral contraceptives.
- past experience with excessive gambling or other compulsive behaviours.
- have or had low white blood cell count.
- other medical conditions including conditions that may affect you receiving an injection in your arm or buttocks.
- take any medicines for any other condition

Tell your doctor if you have past experience of excessive gambling. Tell your doctor if you drink alcohol.

You should avoid alcohol as it could magnify the side effects of this medicine.

If you have not told your doctor about any of the above, tell them before you receive Abilify Maintena.

Ask your doctor or pharmacist for advice before taking any medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Abilify Maintena should not be received during pregnancy unless the benefit outweighs the risk. If you need to receive Abilify Maintena during your pregnancy, your doctor will discuss with you the risks and benefits of taking it.

The following symptoms may occur in newborn babies of mothers that receive Abilify Maintena in the last three months of their pregnancy: shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you need to contact your doctor immediately.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

If you are receiving Abilify Maintena, your doctor will discuss with you whether you should breast-feed considering the benefit to you of your therapy and the benefit to your baby of breast-feeding. You should not do both. Talk to your doctor about the best way to feed your baby if you are receiving Abilify Maintena.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Abilify Maintena may interfere with each other. These include:

- medicines and herbal remedies used to treat depression and anxiety.
- certain medicines used to treat nicotine dependence.
- anticonvulsants used to treat epilepsy.
- medicines used to treat high blood pressure.
- medicines used to treat heart rhythm disturbances.
- medicines used to treat bacterial, fungal or viral infections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Abilify Maintena.

4. How do I use Abilify Maintena?

Abilify Maintena is a long-acting medicine that a healthcare professional will give to you by injection.

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.

Abilify Maintena can be received regardless of meals.

How it is given

Abilify Maintena comes as a therapeutic kit. The kit includes a powder which your healthcare professional will make into a suspension that will then be injected into the muscle in your buttock or shoulder. You may feel a little pain during the injection, which may become less over time.

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

After your first dose you must take 10 mg to 20 mg of oral aripiprazole (or prescribed dose of an 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 straight away.

How many injections you will need?

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

It may take several days to some weeks, sometimes longer, before you feel any improvement.

Your doctor will check your progress at regular intervals.

What if you miss a dose of Abilify Maintena

Abilify Maintena should be used regularly. 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.

If you receive too much Abilify Maintena

This medicine will be given to you under medical supervision. Therefore, it is unlikely that you will be given too much. If you see more than one doctor, be sure to tell them that you are receiving Abilify Maintena.

If you have received too much aripiprazole you may experience:

- rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements

(especially of the face or tongue) and reduced level of consciousness.

- other symptoms may include: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness, and drowsiness or sleepiness; slower breathing, choking, high or low blood pressure, abnormal rhythms of the heart.

If you think that you have received too much Abilify Maintena, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Abilify Maintena?

Things you should do

Call your doctor straight away if you:

- become pregnant.
- are about to be started on any new medicine.

- are going to have surgery that requires a general anaesthetic. Tell your doctor or dentist that you are receiving Abilify Maintena as it may affect other medicines used during surgery.

Remind any doctor, dentist, nurse or pharmacist you visit that you are using Abilify Maintena.

Your doctor will check your progress and may want to take some blood tests from time-to-time. This helps reduce unwanted effects.

Your doctor may also check your body weight before starting Abilify Maintena and continue to monitor it for as long as you are being treated.

Patients and care givers 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.

Things to be careful of

If Abilify Maintena makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Getting up slowly may help.

Abilify Maintena may affect the way your body reacts to temperature changes.

It may prevent sweating, even during heatwaves. You may feel dizzy or faint if you are too hot. To stay cool in hot weather, try to do the following:

- wear light clothing.
- spend time in air-conditioned environments (or keep windows open and use electric fans).
- drink plenty of water.
- take cool baths or showers and avoid hot baths and saunas.
- try to restrict exercise or heavy work to cool parts of the day.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Abilify Maintena affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid alcohol while you are taking Abilify Maintena.

Abilify Maintena can increase the effects of alcohol.

Looking after your medicine

Abilify Maintena will be stored by your healthcare professional until it is time for them to administer the injection to you.

Abilify Maintena should be stored in its package in a dry place where the temperature stays below 30°C. Do not freeze. Your healthcare professional will not use Abilify Maintena beyond the expiry date printed on the carton.

Getting rid of any unwanted medicine

A doctor, nurse or pharmacist will dispose of any unused medicine

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Abilify Maintena.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• headache• fatigue, drowsiness or sleepiness• speech disorder	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● agitation or restlessness ● pain or swelling at the site of injection ● appetite increase or decrease ● shaking ● muscle ache or stiffness ● dry mouth ● difficulty in passing urine or incontinence ● inability for a man to have an erection or a persistent and painful erection ● depression ● blurred or double vision ● abnormal hair loss ● constipation or diarrhoea ● high blood pressure ● abnormal liver blood values ● low sodium levels in the blood ● bruise easily 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or rash, itching or hives, spasm of the muscles around the voice box.).● abnormal movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs.● high fever, stiff muscles, confusion, sweating, and changes in pulse, heart rate, and blood pressure, which may lead to coma. This reaction is called neuroleptic malignant syndrome.● convulsions or seizures.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● chest pain. ● rapid pulse. ● swelling, pain or redness in the leg, chest pain or difficulty in breathing. ● a combination of any of the following: excessive sleepiness, dizziness, confusion, disorientation, difficulty talking, difficulty walking, muscle stiffness or shaking, fever, weakness, irritability, aggression, anxiety, increase in blood pressure, or seizures that lead to loss of consciousness. ● high or unstable blood sugar levels (feeling very thirsty and/or hungry, needing to urinate more often than usual, feeling weak or tired, feeling sick to your stomach, feeling confused, have fruity smelling breath)), or the 	

Serious side effects	What to do
<p>onset or worsening of diabetes.</p> <ul style="list-style-type: none"> ● thoughts of suicide, attempts at suicide or suicide. See also section "Things you must do". ● yellowing of the skin and/or eyes, also called jaundice with or without nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching and dark coloured urine. ● inflammation of the pancreas or liver, severe upper stomach pain often with nausea and vomiting. ● muscle pain, muscle weakness or muscle cramps, high blood levels of the enzyme creatine phosphokinase. ● serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu- 	

Serious side effects	What to do
<p>like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia).</p> <ul style="list-style-type: none"> ● inability to sit or stand still; restless movement of the arms and legs such as tapping, marching in places, rocking, crossing and uncrossing legs ● abnormally low or high body temperature or excessive sweating ● excessive compulsive urges such as gambling, sexual urges, spending, binge or compulsive eating ● feeling dizzy or fainting, especially when getting up from a lying or sitting position, including falls. 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● frequent infections such as fever, severe chills, sore throat or mouth ulcers. ● difficulty swallowing or accidental inhalation of food or liquids with risk of pneumonia. ● weight loss or gain <p>Elderly patients with dementia may suffer serious side effects such as "mini" stroke, stroke, pneumonia, or heart problems. These serious side effects can be life threatening.</p>	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Abilify Maintena contains

Active ingredient (main ingredient)	Abilify Maintena 400 mg therapeutic kit contains 400 mg aripiprazole (as monohydrate) per vial. Abilify Maintena 300 mg therapeutic kit contains 300 mg aripiprazole (as monohydrate) per vial.
Other ingredients (inactive ingredients)	mannitol carmellose sodium sodium hydroxide monobasic sodium phosphate monohydrate

Potential allergens	Abilify Maintena does not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.
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Do not take this medicine if you are allergic to any of these ingredients.

What Abilify Maintena looks like

Abilify Maintena is available as a therapeutic kit. The kit contains either 400 mg or 300 mg of aripiprazole (as monohydrate). The therapeutic kit contains all that is required for your healthcare professional to reconstitute and administer the required dose of medicine to you. After reconstitution, each mL of suspension contains 200 mg of aripiprazole.

The therapeutic kit contains the following items:

- one vial containing a white to off-white powder containing aripiprazole (as monohydrate);
- one vial containing water for injections for mixing with the powder;
- one sterile syringe with a needle;
- one sterile syringe without a needle;
- three safety needles; and
- one vial adapter.

Australian Registration Numbers:

Abilify Maintena 400 mg: AUST R 211150 (Composite pack)

Abilify Maintena 300 mg: AUST R 211122 (Composite pack)

Who distributes Abilify Maintena

Lundbeck Australia Pty Limited
Ground Floor, 1 Innovation Road
North Ryde NSW 2113

Ph: 02 8669 1000

Abilify Maintena is co-marketed by Lundbeck Australia and Otsuka Australia Pharmaceutical:

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