

Abilify Maintena[®]

Powder and solvent for prolonged release suspension for intramuscular injection

Aripiprazole (ari-pip-rah-zol)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Abilify Maintena. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the potential risks of you receiving Abilify Maintena against the expected benefits.

If you have any concerns about receiving this medicine ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Abilify Maintena is used for

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.

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.

You and your doctor have decided on Abilify Maintena to help relieve the symptoms of your condition.

Although Abilify Maintena cannot cure schizophrenia or Bipolar I Disorder, it can help to keep the symptoms under control and reduce the risk of relapse as you continue treatment.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Abilify Maintena is available only with a doctor's prescription.

There is no evidence that Abilify Maintena is addictive.

Abilify Maintena should not be given to children and adolescents under 18 years of age as safety and efficacy have not been established in this age group.

Abilify Maintena should not be taken unless oral Abilify has previously been tolerated.

Before you receive Abilify Maintena

Abilify Maintena should only be given by a healthcare professional.

When you must not receive it

Do not receive 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.

Abilify Maintena should not be used after the expiry date (EXP) printed on the pack. The expiry date refers to the last day of the month.

It may have no effect at all or, an entirely unexpected effect if you receive it after the expiry date.

Abilify Maintena should not be used if the packaging is torn or shows signs of having been tampered with.

If you are not sure whether Abilify Maintena would be beneficial for you, talk to your doctor or pharmacist.

Before you start to receive it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant, think you are pregnant or plan 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.

Tell your doctor if you are breast-feeding or planning to breast-feed.

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.

Tell your doctor if you have or have had any 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.
- 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.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a 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.

These medicines may be affected by Abilify Maintena, or may affect how well it works. You may need to use different amounts of medicines, or take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while receiving this medicine.

If you have not told your doctor or pharmacist about any of these things, tell them before you receive Abilify Maintena.

How to 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 is a kit that 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 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

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.

If you receive too much (overdose)

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 or anyone else may have received too much Abilify Maintena, immediately telephone your doctor or Poisons Information Centre (Telephone 13 11 26) for advice, or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. Keep the telephone number handy.

You may need urgent medical attention.

While you are receiving Abilify Maintena

Things you must do

Tell your doctor immediately if you become pregnant while taking Abilify Maintena.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving Abilify Maintena.

Tell all doctors, dentists and pharmacists who are treating you that you are receiving Abilify Maintena.

If you are going to have surgery that requires a general anaesthetic, tell your doctor or dentist that you are receiving Abilify Maintena.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some blood tests from time-to-time. This helps reduce unwanted effects. Abilify Maintena may be associated with changes in:

- liver blood values,
- muscle enzyme blood levels,
- sodium blood levels,
- blood sugar levels,
- lipid blood levels, or
- white blood cell levels.

Your doctor may 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

Driving or operating machinery should be avoided until you know how Abilify Maintena affects you. 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.

Avoid alcohol while you are taking Abilify Maintena.

Abilify Maintena can increase the effects of alcohol.

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.

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. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- headache
- fatigue, drowsiness or sleepiness
- speech disorder
- agitation or restlessness
- inability to sit or stand still; restless movement of the arms and legs such as tapping, marching in places, rocking, crossing and uncrossing legs
- pain or swelling at the site of injection
- weight loss or gain
- 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
- abnormally low or high body temperature or excessive sweating
- excessive compulsive urges such as gambling, sexual urges, spending, binge or compulsive eating

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

- 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 or accidental inhalation of food or liquids with risk of pneumonia.
- bruise easily.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the side effects listed below.

- 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).
- 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.
- 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 onset or worsening of diabetes.
- 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.
- spasm of the muscles around the voice box.

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.

Other side effects not listed above may also occur in some people. Tell

your doctor or pharmacist if you notice anything else that is making you unwell.

Storage of Abilify Maintena

Storage

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.

Abilify Maintena description

What Abilify Maintena looks like

Abilify Maintena is available in one-month therapeutic kits. A single 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.

Ingredients

Active ingredients

- 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.

Inactive ingredients

Abilify Maintena also contains:

- mannitol
- carmellose sodium
- sodium hydroxide
- monobasic monohydrate sodium phosphate

Abilify Maintena does not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

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

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