Abilify Asimtufii®

Pre-filled syringe

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.

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1. Why am I using Abilify Asimtufii?

Abilify Asimtufii contains the active ingredient aripiprazole. Abilify Asimtufii 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 Asimtufii? in the full CMI.

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

Abilify Asimtufii should only be given by a healthcare professional.

Do not use Abilify Asimtufii 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 Asimtufii? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Abilify Asimtufii 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 Asimtufii?

Abilify Asimtufii 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 Asimtufii? in the full CMI.

5. What should I know while using Abilify Asimtufii?

Things you should do	• Tell your doctor immediately if you become pregnant while taking Abilify Asimtufii. • 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	• If Abilify Asimtufii makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Abilify Asimtufii affects you.
Drinking alcohol	• Avoid alcohol while you are taking Abilify Asimtufii.

Looking after your medicine	• Abilify Asimtufii 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 Abilify Asimtufii? 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 Asimtufii®

Prolonged release suspension for intramuscular injection – pre-filled syringe

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Abilify Asimtufii. **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 Asimtufii.**

Where to find information in this leaflet:

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

1. Why am I using Abilify Asimtufii?

Abilify Asimtufii contains the active ingredient aripiprazole. Abilify Asimtufii belongs to a group of medicines called antipsychotic agents. Abilify Asimtufii

helps to correct a chemical imbalance in the brain which may cause schizophrenia and Bipolar I Disorder.

Abilify Asimtufii 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 Asimtufii to help relieve the symptoms of your condition. Abilify Asimtufii 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 Asimtufii?

Abilify Asimtufii should only be given by a healthcare professional.

Warnings

Do not use Abilify Asimtufii if:

- you are allergic to aripiprazole, or any of the ingredients listed 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 use Abilify Asimtufii.

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 Asimtufii should not be used during pregnancy unless the benefit outweighs the risk. If you need to use Abilify Asimtufii 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 use Abilify Asimtufii 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 using Abilify Asimtufii, 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 using Abilify Asimtufii.

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 Asimtufii 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 Asimtufii.

4. How do I use Abilify Asimtufii?

Abilify Asimtufii 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 every 2 months.

Abilify Asimtufii can be administered regardless of meals.

How it is given

Abilify Asimtufii comes as a pre-filled syringe. The pre-filled syringe contains a suspension which your healthcare professional will prepare that will then be injected into the muscle in your buttock. You may feel a little pain during the injection, which may become less over time.

The usual dose is 960 mg every 2 months (56 days after the previous injection). Your healthcare professional may administer a lower dose if required. Your doctor will decide on the dose of Abilify Asimtufii that is right for you.

There are two ways of starting Abilify Asimtufii 960 mg. Your doctor will decide which way is right for you.

1. After your first dose of Abilify Asimtufii, you must take your prescribed dose of 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.

2. If you are given Abilify Maintena, your next dose may be replaced with one injection of Abilify Asimtufii.

How many injections will you need?

Abilify Asimtufii should be administered to you once every two months (56 days after the previous injection) 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 continue to use Abilify Asimtufii 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 Asimtufii

Abilify Asimtufii 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 2 months.

If you use too much Abilify Asimtufii

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 using Abilify Asimtufii.

If you have been given 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 been given too much Abilify Asimtufii, 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 Asimtufii?

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 using Abilify Asimtufii as it may affect other medicines used during surgery.

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

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 Asimtufii 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 Asimtufii 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 Asimtufii 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 Asimtufii affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid alcohol while you are using Abilify Asimtufii.

Abilify Asimtufii can increase the effects of alcohol.

Looking after your medicine

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

Abilify Asimtufii should be stored in its package in a dry place where the temperature stays below 25°C. Do not freeze. Your healthcare professional will not use Abilify Asimtufii 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 using Abilify Asimtufii.

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

Less serious side effects	What to do
• difficulty swallowing or accidental inhalation of food or liquids with risk of pneumonia. • bruise easily	

Serious side effects

Serious side effects	What to do
• 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	**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.**

Serious side effects	What to do
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	

Serious side effects	What to do
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.	

Serious side effects	What to do
• serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-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). **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.**	

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 Asimtufii contains

Active ingredient **(main ingredient)**	Abilify Asimtufii 960 mg pre-filled syringe contains 960 mg aripiprazole (as monohydrate) per syringe. Abilify Asimtufii 720 mg pre-filled syringe contains 720 mg aripiprazole (as monohydrate) per syringe.
Other ingredients	Carmellose sodium

(inactive ingredients)	Povidone Macrogol 400 Monobasic sodium phosphate monohydrate Sodium chloride Sodium hydroxide Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Abilify Asimtufii looks like

Abilify Asimtufii is available as a therapeutic kit. The kit contains either 960 mg or 720 mg of aripiprazole (as monohydrate). The pre-filled syringe carton contains all that is required for your healthcare professional to administer the required dose of medicine to you. Each mL of suspension contains 300 mg of aripiprazole.

The pre-filled syringe kit contains the following items:

- a pre-filled syringe containing a white to off-white suspension for injection
- two safety needles

Australian Registration Numbers:

Abilify Asimtufii 960 mg: AUST R 410039 (pre-filled syringe)

Abilify Asimtufii 720 mg: AUST R 410032 (pre-filled syringe)

Who distributes Abilify Asimtufii

Lundbeck Australia Pty Limited

Ground Floor, 1 Innovation Road
North Ryde NSW 2113
Ph: 02 8669 1000

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

Otsuka Australia Pharmaceutical Pty. Limited
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