

# ARIZOLE

## 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 this medicine?

This medicine contains the active ingredient aripiprazole. This medicine is used to treat symptoms of schizophrenia.

For more information, see Section [1. Why am I using this medicine?](#) in the full CMI.

### 2. What should I know before I use this medicine?

Do not use if you have ever had an allergic reaction to this medicine 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 this medicine?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with this medicine and affect how it works.

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 this medicine?

- Unless your doctor gives you other directions, you should take this medicine only once a day.
- Take this medicine at about the same time each day.

More instructions can be found in Section [4. How do I use this medicine?](#) in the full CMI.

### 5. What should I know while using this medicine?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using this medicine.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.</li><li>• Do not stop taking this medicine or lower the dosage, even if you are feeling better, without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Make sure that you know how you react to this medicine before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light headed or not alert.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while taking this medicine.</li><li>• Your doctor may suggest you avoid alcohol while you are being treated with this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store this medicine in a cool place where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

Common side effects are headache; indigestion; nausea; vomiting; insomnia; constipation; light-headedness; drowsiness; agitation; anxiety; inability to sit or stand still, restless movement of the arms and legs. Serious side effects include seizure; fits or convulsions; fainting; sudden increase in body temperature; sweating.

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.

# ARIZOLE

Active ingredient: *Aripiprazole*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using this medicine. **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 this medicine.**

Where to find information in this leaflet:

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

## 1. Why am I using this medicine?

**This medicine contains the active ingredient aripiprazole.**

This medicine belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

**This medicine is used to treat symptoms of schizophrenia.**

Schizophrenia is a mental illness with disturbances in thinking, feelings and behaviour.

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

There is no evidence that this medicine is addictive.

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

This medicine is not recommended for use in children under the age of 18, as safety and efficacy have not been established in this age group.

## 2. What should I know before I use this medicine?

### Warnings

**Do not use this medicine 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.

Symptoms of an allergic reaction include:

- rash, itching or hives on the skin.
- shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, throat or other parts of the body.

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines.
- any other substances such as foods, preservatives or dyes.

**Do not take this medicine after the expiry or use by date printed on the pack.**

If you take this medicine after this date has passed, it may not work as well.

**Do not take this medicine if the packaging is torn or shows signs of tampering.**

If this is the case, return it to your pharmacist.

**If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.**

**Check with your doctor if you:**

- Have any other medical conditions especially the following:
  - A 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. This reaction is called neuroleptic malignant syndrome.
  - 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. This reaction is called tardive dyskinesia.
  - Low blood pressure.
  - Problems with your heart or blood vessels.
  - Epilepsy, seizures or fits.
  - Problems with your oesophagus (food pipe) such as difficulty in swallowing.
  - High blood sugar or diabetes mellitus.
  - Alzheimer's disease or dementia.
  - Alcohol or drug abuse or dependence or a history of one of these.
  - Venous thromboembolism or are at risk of venous thromboembolism.
  - Have a history of or are at risk of sleep apnoea (a sleep disorder where your breathing is interrupted during sleep).
  - Lactose intolerance.
- Take any medicines for any other condition.

**Your doctor may need to adjust or stop your dose.**

**All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts, feelings about hurting yourself or other significant mood changes.**

**Suicidal thoughts and behaviours have been reported during treatment with this medicine.**

### **Tell your doctor if you drink alcohol.**

Your doctor may advise you to avoid alcohol as it can magnify the side-effects of this medicine.

**Aripiprazole may cause sleepiness, fall in blood pressure when standing up, dizziness and changes in your ability to move and balance, which may lead to falls. Caution should be taken.**

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking this 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.

This medicine is not recommended for use during pregnancy. If you need to take this medicine during your pregnancy, your doctor will discuss with you the benefits and risks of taking it. Babies exposed to antipsychotics (including this medicine) during the third trimester of pregnancy are at risk of experiencing shaking, muscle stiffness, difficulty in feeding and/or withdrawal symptoms. These symptoms may resolve spontaneously or require additional medical treatment.

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

It is recommended that you do not breast-feed while taking this medicine, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

### **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 may interfere with this medicine and affect how it works. These include:**

- medicines used to treat brain disorders such as, anxiety, depression, mood swings, epilepsy or seizures, Parkinson's disease or insomnia.
- medicines used to treat high blood pressure.
- medicines used to treat fungal infections.
- medicines used to treat heart rhythm disturbances.
- medicines used to treat bacterial or viral infections.
- a medicine called ciclosporin (Neoral®; Sandimmun®).
- a medicine called cimetidine (Tagamet®; Magicul®).

These medicines may be affected by this medicine or may affect how well it works. Your doctor may need to adjust your dose of medicine or of the other medicine.

Eating grapefruit or drinking grapefruit juice may affect how this medicine works.

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

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

### **4. How do I use this medicine?**

#### **How much to take/use**

- Unless your doctor gives you other directions, you should take this medicine only once a day.
- Tablets should be swallowed whole and washed down with a glass of water.
- Follow the instructions provided and use this medicine until your doctor tells you to stop.
- This medicine helps to control your condition but does not cure it. Therefore you must take this medicine every day. Improvement in symptoms may take several days to some weeks to occur. Even if you feel better do not stop taking this medicine unless your doctor tells you to.

#### **When to take/use this medicine**

- Take this medicine at about the same time each day.  
Taking the medicine at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter whether you take this medicine with or without food.

#### **If you forget to use this medicine**

This medicine should be used regularly at the same time each day. If you miss your dose at the usual time, follow the instructions below:

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

**If you use too much of this medicine.**

If you think that you have used too much of this medicine, you may need urgent medical attention.

Patients who have taken too much of this medicine have experienced the following symptoms:

- drowsiness or sleepiness
- high blood pressure
- rapid heartbeat
- vomiting
- reduced level of consciousness

**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 this medicine?

### Things you should do

- If you are about to start on any new medicine, tell your doctor, dentist and pharmacist that you are taking this medicine.
- If you plan to have any kind of surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.
- Be sure to keep all of your doctor's appointments so that your progress can be checked.

**Call your doctor straight away if you:**

- Become pregnant while taking this medicine.

Remind any doctor, dentist or pharmacist you visit that you are using this medicine.

### Things you should not do

- **Do not give this medicine to anyone else, even if their symptoms seem similar or they have the same condition as you.**
- **Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.**
- **Do not stop taking this medicine or lower the dosage, even if you are feeling better, without checking with your doctor.** If you stop taking this medicine suddenly your condition may worsen.
- **Do not take more of this medicine and do not take it more often than your doctor has ordered.**

**Make sure you keep cool in hot weather and keep warm in cool weather.**

This medicine 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 and showers and avoid hot baths and saunas.
- Try to restrict exercise or heavy work to cool parts of the day.

### Driving or using machines

**Make sure that you know how you react to this medicine before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or light headed or not alert.**

This medicine may cause some people to become drowsy or less alert than they are normally or cause light-headedness, dizziness or tiredness. If this occurs do not undertake the activity.

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

Getting up slowly may help.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

**Be careful when drinking alcohol while taking this medicine.**

Your doctor may suggest you avoid alcohol while you are being treated with this medicine.

### Looking after your medicine

**Store this medicine in a cool place where the temperature stays below 25°C.**

Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Do not keep outdated medicine or medicine no longer needed.

### When to discard your medicine

**If your doctor tells you to stop taking this medicine or the medicine has passed its expiry date, ask your pharmacist what to do with any leftover medicine.**

**Be sure that any discarded medicine is out of the reach of children.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

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.

This medicine is generally well-tolerated and the side effects are often hard to distinguish from disease symptoms. It is important that you tell your doctor as soon as possible about any unwanted effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• Indigestion</li> <li>• Vomiting</li> <li>• Constipation</li> </ul> <p><b>Pain related:</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Chest pain</li> </ul> <p><b>General well-being related:</b></p> <ul style="list-style-type: none"> <li>• Insomnia</li> <li>• Light headiness</li> <li>• Drowsiness</li> <li>• Agitation</li> <li>• Anxiety</li> <li>• Inability to sit or stand still; restless movement of the arms and legs such as tapping, marching in places, rocking, crossing and uncrossing the legs.</li> <li>• Feeling dizzy especially when getting up from a lying or sitting position.</li> <li>• Altered or increased sexual interest.</li> <li>• High blood sugar (excessive thirst, hunger and weakness) or the onset of worsening diabetes.</li> <li>• Weight gain.</li> <li>• Weight loss.</li> <li>• Loss of appetite.</li> <li>• Excessive sweating.</li> <li>• Drowsiness.</li> <li>• High blood pressure.</li> <li>• Difficulty swallowing.</li> <li>• Hiccups.</li> <li>• Nausea.</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>• Frequent infections such as fever, severe chills, sore throat or mouth ulcers.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>• Bleeding or bruising more easily than normal.</li> </ul> <p><b>Speech related:</b></p> <ul style="list-style-type: none"> <li>• Speech disorder.</li> </ul> <p><b>Bladder related:</b></p> <ul style="list-style-type: none"> <li>• Urinary incontinence.</li> </ul>	

### Serious side effects

Serious side effects	What to do
<p><b>Pain related:</b></p> <ul style="list-style-type: none"> <li>• Muscle pain, muscle weakness or muscle stiffness.</li> <li>• Painful irreversible erection.</li> </ul> <p><b>General well-being related:</b></p> <ul style="list-style-type: none"> <li>• Seizure, fits or convulsions.</li> <li>• Fainting.</li> <li>• Abnormal movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, eyes or jaw which may progress to the arms and legs.</li> <li>• Sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions.</li> <li>• Disorder of the body temperature regulation resulting in low body temperature or high body temperature.</li> <li>• 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.</li> </ul> <p><b>Allergy related:</b></p> <ul style="list-style-type: none"> <li>• Rash.</li> <li>• Allergic reaction (rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body) with or without fever.</li> </ul> <p><b>Inflammation related:</b></p> <ul style="list-style-type: none"> <li>• Inflammation of the pancreas, severe upper stomach pain often with nausea and vomiting.</li> </ul> <p><b>Infection related:</b></p> <ul style="list-style-type: none"> <li>• Serious lung infection with fever, chills, shortness of breath,</li> </ul>	<p><b>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.</b></p>

Serious side effects	What to do
<p>cough, chest pain and blood-streaked phlegm.</p> <p><b>Bladder related:</b></p> <ul style="list-style-type: none"> <li>• Difficulty in passing urine.</li> </ul> <p><b>Mental related:</b></p> <ul style="list-style-type: none"> <li>• Thoughts or talk about death or suicide, thoughts or talk about self-harm or doing harm to others, any recent attempts at self-harm, an increase in aggressive behaviour, irritability or agitation. If you or someone you know is showing these signs contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment.</li> </ul>	

**Tell your doctor if you have obsessive (recurring) thoughts or behaviours or trouble controlling impulsive urges while taking this medicine.**

Obsessive compulsive behaviours (feeling the need to check things repeatedly or having certain thoughts repeatedly), gambling urges, sexual urges, compulsive spending, binge or compulsive eating and other urges have occurred in some patients.

**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.**

Also, while taking this medicine, some elderly patients with dementia have suffered serious side effects such as a "mini" stroke, stroke, pneumonia or heart problems. These serious side effects can be life threatening.

**Do not be alarmed by this list of possible side effects.**

You may not experience any or only some of them.

**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](http://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 this medicine contains**

<b>Active ingredient (main ingredient)</b>	Aripiprazole
<b>Other ingredients</b>	<ul style="list-style-type: none"> <li>• Lactose monohydrate</li> <li>• Microcrystalline cellulose</li> </ul>

<b>(inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Maize starch</li> <li>• Hyplose</li> <li>• Colloidal anhydrous silica</li> <li>• Magnesium stearate</li> <li>• Indigo carmine aluminium lake C173015 (2 mg and 5 mg tablets)</li> <li>• Iron oxide yellow C177492 (2 mg tablets)</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>• Lactose monohydrate</li> </ul>

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

**What this medicine looks like**

**ARIZOLE 2, 2 mg Tablets\***

Green, coloured, modified rectangular shaped uncoated tablets debossed with '61' on one side and 'H' on other side.

ARTG 198211 (blister pack), ARTG 198199 (bottle).

**ARIZOLE 5 mg Tablets**

Blue coloured, modified rectangular shaped, uncoated tablets debossed with '62' on one side and 'H' on other side.

ARTG 198209 (blister pack), ARTG 198207 (bottle).

**ARIZOLE 10 mg Tablets**

White coloured, modified rectangular shaped, uncoated tablets debossed with '63' on one side and 'H' on other side.

ARTG 198179 (blister pack), ARTG 198197 (bottle).

**ARIZOLE 15 mg Tablets**

White coloured, round shaped, uncoated tablets debossed with '64' on one side and 'H' on other side.

ARTG 198204 (blister pack), ARTG 198189 (bottle).

**ARIZOLE 20 mg Tablets**

White coloured, round shaped, uncoated tablets debossed with '65' on one side and 'H' on other side.

ARTG 198193 (blister pack), ARTG 198178 (bottle).

**ARIZOLE 30 mg Tablets**

White coloured, round shaped, uncoated tablets debossed with '66' on one side and 'H' on other side.

ARTG 198196 (blister pack), ARTG 198200 (bottle).

\*Not marketed in Australia.

**Who distributes this medicine**

Arrow Pharma Pty Ltd

15 - 17 Chapel street

Cremorne VIC 3121

This leaflet was prepared in May 2023.