

Aripiprazole GH

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 Aripiprazole GH?

Aripiprazole GH contains the active ingredient aripiprazole. Aripiprazole GH is used to treat symptoms of schizophrenia. Aripiprazole GH may be given to treat acute episodes of sustained upward mood swings (mania) in adult patients with Bipolar 1 Disorder. During mania, patients experience episodes of overactivity, elation or irritability.

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

2. What should I know before I use Aripiprazole GH?

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

3. What if I am taking other medicines?

Some medicines may interfere with Aripiprazole GH 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 Aripiprazole GH?

- Unless your doctor gives you other directions, you should take Aripiprazole GH only once day.
- Take Aripiprazole GH at about the same time each day. Tablets should be swallowed whole with a glass of water.

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

5. What should I know while using Aripiprazole GH?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Aripiprazole GH.• If you become pregnant while taking Aripiprazole GH, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not give Aripiprazole GH to anyone else, even if their symptoms seem similar or they have the same conditions as you.• Do not stop taking Aripiprazole GH or lower the dosage, even if you are feeling better, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Make sure that you know how react to Aripiprazole GH 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.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking Aripiprazole GH• Your doctor may suggest you avoid
Looking after your medicine	<ul style="list-style-type: none">• Store Aripiprazole GH in a cool place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Aripiprazole GH?](#) 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 seizures; 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.

Aripiprazole GH

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using Aripiprazole GH. **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 Aripiprazole GH.**

Where to find information in this leaflet:

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

1. Why am I using Aripiprazole GH?

Aripiprazole GH contains the active ingredient aripiprazole. Aripiprazole GH belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

Aripiprazole GH is used to treat symptoms of schizophrenia.

Aripiprazole GH may be given to treat acute episodes of sustained upward mood swings (mania) in adult patients with Bipolar 1 Disorder. During mania, patients experience episodes of overactivity, elation or irritability.

Schizophrenia is a mental illness with disturbances in thinking, feeling and behaviours.

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.

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

There is no evidence that Aripiprazole GH is addictive.

2. What should I know before I use Aripiprazole GH?

Warnings

Do not use Aripiprazole GH 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.
- the packaging shows signs of tampering.

- the expiry date on the pack has passed. If you use this product after the expiry date has passed, it may not work.

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.

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, muscles 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 history of one of these.
 - venous thromboembolism or you are at risk of venous thromboembolism.
 - 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.

Tell your doctor if you have past experience of excessive gambling

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 Aripiprazole GH.

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.

Aripiprazole GH is not recommended for use during pregnancy. If you need to take Aripiprazole GH during your pregnancy, your doctor will discuss with you the benefits and risks of taking it. Babies exposed to antipsychotics (including Aripiprazole GH) 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 breastfeed while taking Aripiprazole GH, as it may pass into breast milk and therefore there is a possibility that the breastfed 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 that you get without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with Aripiprazole GH 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 cyclosporin (Neoral; Sandimmun).
- a medicine called cimetidine (Magicul).

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

Eating grapefruit or drinking grapefruit juice may affect how Aripiprazole GH works.

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

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

4. How do I use Aripiprazole GH?

How much to take/use

- Unless your doctor gives you other directions, you should take Aripiprazole GH only once a day.

- Aripiprazole GH tablets should be swallowed whole and washed down with a glass of water
- Follow the instructions provided and use Aripiprazole GH until your doctor tells you to stop.
- Aripiprazole GH helps to control your condition but does not cure it. Therefore you must take ABILIFY every day. Improvement in symptoms may take several days to some weeks to occur. Even if you feel better do not stop taking Aripiprazole GH unless your doctor tells you to.

When to take/use Aripiprazole GH

- Take Aripiprazole GH 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 Aripiprazole GH with or without food.

If you forget to use Aripiprazole GH

Aripiprazole GH 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 injection when you are meant to.

Otherwise, take it as soon as 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 having an unwanted side effect.

If you are not sure what to do, ask your doctor or healthcare professional.

If you use too much Aripiprazole GH

If you think that you have used too much Aripiprazole GH, you may need urgent medical attention.

Symptoms of an overdose may include high blood serum calcium levels, dizziness, or light-headedness on standing up. Nausea, vomiting, dizziness, and headache may also occur.

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 Aripiprazole GH?

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Aripiprazole GH.
- If you plan to have any kind of surgery that needs a general anaesthetic, tell the surgeon or anaesthetist that you are taking Aripiprazole GH.
- Be sure to keep all of your doctor's appointments so that your progress can be checked.
- Make sure you keep cool in hot weather and keep warm in cool weather. Aripiprazole GH 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.

Call your doctor straight away if you:

- become pregnant while using this medicine.

Remind any doctor, dentist pharmacist, or anaesthetist you visit that you are using Aripiprazole GH.

Things you should not do

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

Driving or using machines

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

Aripiprazole GH 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 Aripiprazole GH 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.

Your doctor may advise you to avoid alcohol while you are being treated with Aripiprazole GH as it can magnify the side effects of this medicine.

Be careful when drinking alcohol while taking Aripiprazole GH.

Looking after your medicine

- Store Aripiprazole GH below 30°C.

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, 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.

When and how to discard your medicine

If your doctor tells you to stop taking Aripiprazole GH or the medicine has passed 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.

Aripiprazole GH 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
Gastrointestinal related: <ul style="list-style-type: none">• Indigestion.• Vomiting.• Constipation. Pain related: <ul style="list-style-type: none">• Headache.	Speak to your doctor if you have any of these less serious side

<ul style="list-style-type: none"> • Chest pain. <p>General well-being related:</p> <ul style="list-style-type: none"> • Insomnia. • Light-headedness. • Drowsiness. • Agitation. • Anxiety. • 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. • Feeling dizzy especially when getting up from a lying or sitting position. • Altered or increased sexual interest. • High blood sugar (excessive thirst, hunger and weakness) or the onset of worsening of diabetes. • Weight gain. • Weight loss. • Loss of appetite. • Excessive sweating. • Drowsiness. • High blood pressure. • Difficulty swallowing. • Hiccups. • Nausea. <p>Infection related:</p> <ul style="list-style-type: none"> • Frequent infections such as fever, severe chills, sore throat or mouth ulcers. <p>Bleeding related:</p> <ul style="list-style-type: none"> • Bleeding or bruising more easily than normal. <p>Speech related:</p> <ul style="list-style-type: none"> • Speech disorder. <p>Bladder related:</p> <ul style="list-style-type: none"> • Urinary incontinence. 	<p>effects and they worry you.</p>
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<ul style="list-style-type: none"> • Sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions. • Disorder of body temperature regulation resulting in low body temperature or high body temperature. • 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. <p>Allergy related:</p> <ul style="list-style-type: none"> • Rash. • 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. <p>Inflammation related:</p> <ul style="list-style-type: none"> • Inflammation of the pancreas, severe upper stomach pain often with nausea and vomiting. <p>Infection related:</p> <ul style="list-style-type: none"> • Serious lung infection with fever, chills, shortness of breath, cough, chest pain and blood streaked phlegm. <p>Bladder related:</p> <ul style="list-style-type: none"> • Difficulty in passing urine. <p>Mental related:</p> <ul style="list-style-type: none"> • 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 behaviours, irritability or agitation. If you or someone you know is showing these signs contact your doctor or mental health advisor right away or go to the nearest hospital for treatment. <p>Elderly patients with dementia:</p> <ul style="list-style-type: none"> • While taking Aripiprazole GH, 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. 	
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Serious side effects

Serious side effects	What to do
<p>Pain related:</p> <ul style="list-style-type: none"> • Muscle pain, muscle weakness or muscle stiffness. <p>General well-being related:</p> <ul style="list-style-type: none"> • Seizure, fits or convulsions. • Fainting. • 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. 	<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>

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

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.

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 Aripiprazole GH contains

Active ingredient (main ingredient)	Aripiprazole
Other ingredients (inactive ingredients)	Lactose monohydrate Microcrystalline cellulose Maize starch Hyprolose Magnesium stearate
Potential allergens	Lactose monohydrate

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

What Aripiprazole GH looks like

Aripiprazole GH 5 mg tablets are white, round, biconvex, beveled-edged, uncoated tablets plain on both sides (AUST R 176806).

Aripiprazole GH 10 mg tablets are white, oval-shaped, biconvex, beveled-edged, uncoated tables plain on both sides (AUST R 176808).

Aripiprazole GH 15 mg tablets are white, round, biconvex, beveled-edged, uncoated tablets plain on both sides (AUST R 176810).

Aripiprazole GH 20 mg tablets are white, round, biconvex, uncoated tablets plain on both sides (AUST R 176813).

Aripiprazole GH 30 mg tablets are white, round, biconvex, beveled-edged, uncoated tablets plain on both sides (AUST R 176815).

Who distributes Aripiprazole GH

Generic Health Pty Ltd

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