

ARDIX LURASIDONE

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.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using ARDIX LURASIDONE?

ARDIX LURASIDONE contains the active ingredient [insert active ingredient]. ARDIX LURASIDONE is used to treat adults and adolescents (aged 13 years and over) with schizophrenia. It is only available with a doctor's prescription. For more information, see Section [1. Why am I using ARDIX LURASIDONE?](#) in the full CMI.

2. What should I know before I use ARDIX LURASIDONE?

Do not use if you have ever had an allergic reaction to ARDIX LURASIDONE 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. **ARDIX LURASIDONE is not approved for treatment of elderly patients with dementia-related psychosis or behavioural disorders.** For more information, see Section [2. What should I know before I use ARDIX LURASIDONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARDIX LURASIDONE 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 ARDIX LURASIDONE?

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines. Unless your doctor gives you other directions, you should take ARDIX LURASIDONE only once a day. Take ARDIX LURASIDONE during or immediately after food, consider evening meal. More instructions can be found in Section [4. How do I use ARDIX LURASIDONE?](#) in the full CMI. **Continue taking the tablets for as long as your doctor tells you.**

5. What should I know while using ARDIX LURASIDONE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARDIX LURASIDONE.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking ARDIX LURASIDONE, or lower the dosage, even if you are feeling better, without checking with your doctor.• Do not take any other medications, whether they require a prescription or not, without telling your doctor you are taking ARDIX LURASIDONE as sometimes the action of one medicine may interfere with another.• Avoid grapefruit and grapefruit juice while taking ARDIX LURASIDONE.

<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Do not drive or operate machinery until you know how ARDIX LURASIDONE affects you. Speak with your doctor about when you can resume these activities.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> • Talk to your doctor about how much alcohol you drink. People who drink excessive quantities of alcohol should not take ARDIX LURASIDONE.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Keep your tablets in the pack until it is time to take them. Keep them in a cool dry place where the temperature stays below 30°C. Keep it where children cannot reach them.

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

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. Severe allergic reactions and other severe reactions such as nervous system or musculoskeletal related disorders have rarely been reported. Medical attention or hospitalisation may then be required and should be sought urgently from a doctor or Accident and Emergency at the nearest hospital. 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.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ARDIX LURASIDONE

Active ingredient(s): Lurasidone Hydrochloride
(pronounced lu-ra-si-done hy-dro-chl-ride)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARDIX LURASIDONE. **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 ARDIX LURASIDONE.**

Where to find information in this leaflet:

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

1. Why am I using ARDIX LURASIDONE?

ARDIX LURASIDONE contains the active ingredient lurasidone hydrochloride.

ARDIX LURASIDONE belongs to a group of medicines called atypical antipsychotics. It helps to correct chemical imbalances in the brain, which may cause mental illness.

ARDIX LURASIDONE is used to treat adults and adolescents (aged 13 years over with schizophrenia).

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

Your doctor may have prescribed ARDIX LURASIDONE for another reason.

Ask your doctor if you have any questions about why ARDIX LURASIDONE has been prescribed for you.

ARDIX LURASIDONE is not addictive or habit forming.

ARDIX LURASIDONE is available only with a doctor's prescription.

ARDIX LURASIDONE is not recommended for use in children or adolescents under 13 years of age, as safety and effectiveness have not been established in this age group.

ARDIX LURASIDONE is not approved for the treatment of elderly patients with dementia-related psychosis or behavioural disorders. Medicines like ARDIX

LURASIDONE can increase the risk of death in elderly people who have memory loss (dementia).

2. What should I know before I use ARDIX LURASIDONE?

There are some people who shouldn't take ARDIX LURASIDONE. Please read the list below. If you think any of these situations apply to you or you have any questions, please see your doctor.

Warnings

Do not use ARDIX LURASIDONE if:

- **you are allergic to lurasidone hydrochloride, or any of the ingredients listed at the end of this leaflet.**
- **always check the ingredients to make sure you can use this medicine.**
- **you are taking medicines that can affect how your body processes ARDIX LURASIDONE such as:**
 - **ketoconazole or voriconazole, used to treat certain - fungal infections**
 - **ritonavir, used to treat HIV infection**
 - **carbamazepine, used to treat convulsions (fits)**
 - **phenytoin, used to treat convulsions (fits) and some - heart conditions**

- rifampicin or clarithromycin, used to treat bacterial infections

- herbal medicines derived from St. John's wort, used to treat depression

- **the packaging is torn or shows signs of tampering**
- **the expiry date (EXP) printed in the pack has passed**

If you are not sure whether you should start taking ARDIX LURASIDONE, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes

Talk to your doctor about how much alcohol you drink. People who drink excessive quantities of alcohol should not take ARDIX LURASIDONE.

If you have any doubts or questions about taking ARDIX LURASIDONE consult your doctor.

Check with your doctor if you have or have had:

- dementia-related psychosis (particularly in the elderly)
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body

temperature, extremely high blood pressure and severe convulsions (fits)

- tardive dyskinesia, a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaws which may progress to the arms and legs
- diseases of the blood with a reduced number of white blood cells (e.g. leukopenia or neutropenia) which may result in fever or other signs of infection.
- diabetes, increased blood sugar (also known as hyperglycaemia), or have a family history of diabetes or high blood sugar.
- seizures
- suicidal thoughts or behaviour
- cardiovascular disease (e.g. heart failure, history of heart attack, ischemia, conduction abnormalities, or have a condition known as QT prolongation)
- changed levels of lipids such as cholesterol, triglycerides etc. in the blood (also known as dyslipidemia)
- high blood pressure (also known as hypertension) or low blood pressure (also known as hypotension) or fainting
- venous thromboembolism (e.g. blockage of a blood vessel by a blood clot formed elsewhere in the body)
- cerebrovascular disease (e.g. stroke, dehydration, low blood pressure), particularly in the elderly
- liver or kidney problems
- breast cancer, pituitary tumours (e.g. tumours at the base of the brain)

- high prolactin levels (which may present as breast swelling, unusual secretions of breast milk, missed or irregular menstrual periods, breast enlargement in men or impotence)
- difficulty swallowing
- weight gain
- sleep apnoea (temporarily stopping breathing while sleeping)

Tell your doctor if you are participating in activities that may contribute to an elevation in core body temperature (e.g. exercising strenuously, exposure to extreme heat) or subject you to dehydration.

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

Tell your doctor if you are pregnant or intend to become pregnant.

Like most atypical antipsychotic medicines, ARDIX LURASIDONE is not recommended for use during pregnancy. However, if you need to take ARDIX LURASIDONE during your pregnancy, your doctor will discuss with you the benefits and risks of taking it.

Newborn babies exposed to antipsychotic medicines (including ARDIX LURASIDONE) during the third trimester of pregnancy are at risk of experiencing unusual movements of trembling and/or withdrawal symptoms following delivery including breathing

problems, difficulty in feeding, spasms, restlessness, drowsiness.

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

It is recommended that you do not breast-feed while taking ARDIX LURASIDONE, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected. Be sure you have discussed with your doctor the risks and benefits of using this medicine while breast-feeding.

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

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 ARDIX LURASIDONE and affect how it works. Medicines that can affect how your body processes ARDIX LURASIDONE include:

- ketoconazole or voriconazole, used to treat certain fungal infections
- ritonavir, used to treat HIV infection
- carbamazepine, used to treat convulsions (fits)

- phenytoin, used to treat convulsions (fits) and some heart conditions
- rifampicin or clarithromycin, used to treat bacterial infections
- herbal medicines derived from St. John's wort, used to treat depression

These medicines may be affected by ARDIX LURASIDONE or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

4. How do I use ARDIX LURASIDONE?

How much to take

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Do not change your dose without the advice of your doctor even if you feel better.

Follow the instructions provided and take ARDIX LURASIDONE until your doctor tells you to stop.

When to take ARDIX LURASIDONE

- Swallow ARDIX LURASIDONE whole with a glass of water. Do not chew the tablets.
- ARDIX LURASIDONE should be taken during or immediately after food, consider evening meal.
- Unless your doctor gives you other directions, you should take ARDIX LURASIDONE only once a day.

How to take ARDIX LURASIDONE

Continue taking the tablets for as long as your doctor tells you.

ARDIX LURASIDONE helps control your condition but does not cure it. Therefore you must take ARDIX LURASIDONE every day.

Do not stop taking it unless your doctor tells you to – even if you feel better.

If you forget to take ARDIX LURASIDONE

ARDIX LURASIDONE should be used regularly at the same time each day. If you miss your dose at the usual time, **take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

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 take too much ARDIX LURASIDONE

It is important that you do not take more ARDIX LURASIDONE tablets than your doctor has prescribed.

If you think that you have used too much ARDIX LURASIDONE, you may need urgent medical attention.

If you take too much, you may experience:

- fast, slow or irregular heartbeat
- low blood pressure (i.e. dizziness, light-headedness)

- reduced alertness
- seizures (i.e. fits)
- uncontrolled muscle spasms affecting the head and neck

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.
- If anyone accidentally swallows any of your ARDIX LURASIDONE tablets, call your nearest Poisons Information Centre for advice (Australian telephone: 13 11 26), or go to Accident and Emergency at your nearest hospital. Keep the telephone number for those places handy whilst taking any medications.

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

5. What should I know while using ARDIX LURASIDONE?

Things you should do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking ARDIX LURASIDONE if:

- **you are about to be started on any new medicines**

- **you plan to have surgery that needs a general anaesthetic**
- **you become pregnant while taking ARDIX LURASIDONE**
- **you need to have any medical tests while you are taking ARDIX LURASIDONE**
- you have signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- you have hyperglycaemia (high blood sugar)
- you have a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions (these symptoms may be associated with a condition called 'neuroleptic malignant syndrome')
- dizziness on standing up, especially when getting up from a sitting or lying position (orthostatic hypotension) or fainting
- high blood prolactin levels (which may present as breast swelling, unusual secretion of breast milk, missed or irregular menstrual periods, breast enlargement in men or impotence)

ARDIX LURASIDONE may affect the results of some tests.

Do not take any other medications, whether they require a prescription or not, without first telling your doctor that you are taking ARDIX LURASIDONE as sometimes the action of one medicine may interfere with another.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Avoid eating grapefruit or drinking grapefruit juice during treatment with ARDIX LURASIDONE. Grapefruit and grapefruit juice may affect the amount of ARDIX LURASIDONE in your blood.

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

Call your doctor straight away if you:

If you have any thoughts about suicide or doing harm to yourself, call your doctor immediately and also contact someone you trust.

All thoughts or talk about suicide or violence towards others or yourself are serious.

If you or someone you know is showing any of the following common warning signs, either contact your doctor or healthcare professional or go to the nearest hospital for treatment:

- worsening symptoms of depression or anxiety
- thoughts or talk about death or suicide
- thoughts or talk about self-harm or doing harm to others
- any recent attempts of self-harm

- an increase in aggressive behaviour, irritability or agitation

If someone you know shows any of these symptoms, suggest they urgently contact a healthcare professional.

In addition to talking to your doctor, confidential support and counselling services are available (in Australia) from LifeLine by calling 13 11 14.

Remind any doctor, dentist or pharmacist you visit that you are using ARDIX LURASIDONE.

Things you should not do

Do not stop taking ARDIX LURASIDONE, or lower the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking ARDIX LURASIDONE suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase.

To prevent this, your doctor may gradually reduce the amount of ARDIX LURASIDONE you take each day before stopping completely.

Do not take ARDIX LURASIDONE to treat any other complaints unless your doctor tells you to.

Do not take any medicines that cause drowsiness while you are taking ARDIX LURASIDONE, unless recommended by your doctor.

You should not take ARDIX LURASIDONE together with certain medications (see also under “Do not use ARDIX LURASIDONE if”) as they can affect how your body processes ARDIX LURASIDONE.

Do not give ARDIX LURASIDONE to anyone else, even if their symptoms seem similar or they have the same condition as you.

Things to be careful of

Grapefruit and grapefruit juice should be avoided while taking ARDIX LURASIDONE.

Grapefruit juice contains one or more components that alter the metabolism of some medicines including ARDIX LURASIDONE. This may lead to higher and unpredictable levels of ARDIX LURASIDONE in the blood.

Do not become too hot or dehydrated while taking ARDIX LURASIDONE as your body’s ability to reduce core body temperature may be affected.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARDIX LURASIDONE affects you. Speak with your doctor about when you can resume these activities.

As with other antipsychotic medicines, ARDIX LURASIDONE has the potential to impair judgement, thinking or motor skills in some people. Make sure you know how you react to ARDIX LURASIDONE before

you drive a car, operate machinery, or do anything else that could be dangerous if you are affected by ARDIX LURASIDONE.

Drinking alcohol

Tell your doctor if you drink alcohol. Talk to your doctor about how much alcohol you drink.

People who drink excessive quantities of alcohol should not take ARDIX LURASIDONE.

Looking after your medicine

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.

When to discard your medicine (as relevant)

Discard the medicine when the expiry date (EXP) printed on the pack has passed.

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.

Serious side effects

Serious side effects	What to do
<p data-bbox="199 965 746 1305">Severe allergic reaction exists with any medication. The following are general signs and symptoms of an allergic reaction:</p> <ul data-bbox="199 1339 774 1816" style="list-style-type: none"><li data-bbox="199 1339 667 1442">● skin rash, itching or hives<li data-bbox="199 1464 774 1630">● swelling of the face, lips, tongue or other parts of the body<li data-bbox="199 1653 699 1816">● shortness of breath, wheezing or difficulty breathing <p data-bbox="199 1839 678 1995">Musculoskeletal and connective tissue disorders:</p>	<p data-bbox="809 965 1378 1361">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"> ● temporary paralysis, weakness of muscles or muscle pain ● severe spasms in the muscles of the shoulders, neck and upper body <p>Nervous system disorders:</p> <ul style="list-style-type: none"> ● worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs ● Neuroleptic malignant syndrome (NMS) a serious condition that can lead to death. Symptoms include: sudden increase in body temperature, confusion, sweating, fast heartbeat, muscle stiffness, high blood pressure ● seizures <p>Psychiatric disorders:</p>	

Serious side effects	What to do
<ul style="list-style-type: none"> ● suicidal thoughts or behaviour <p>Vascular disorders:</p> <ul style="list-style-type: none"> ● stroke (cerebrovascular problems) in elderly people with dementia# related psychosis that can lead to death ● sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness, heat or swelling in the arms and legs (these symptoms may be associated with a blockage in the blood vessels) <p>Blood and Lymphatic System Disorders:</p> <ul style="list-style-type: none"> ● frequent infections such as fever, severe chills, sore throat or mouth ulcers 	

Less serious side effects

Less serious side effects	What to do
<p>Psychiatric disorders:</p> <ul style="list-style-type: none">• restlessness, agitation, anxiety• extrapyramidal symptoms including Parkinsonism (e.g. unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, rigid posture, stiffness of the arms and legs, slow movements and a shuffling, unbalanced walk) <p>Nervous system disorders:</p> <ul style="list-style-type: none">• dizziness• sleepiness (somnolence), difficulty sleeping (insomnia) <p>Gastrointestinal disorders:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● feeling sick (nausea), vomiting, ● diarrhoea, abdominal pain, indigestion, decreased appetite, increased saliva, difficulty swallowing <p>Reproductive system and breast disorders:</p> <ul style="list-style-type: none"> ● breast swelling, unusual secretion of breast milk, missed or irregular menstrual periods. Breast enlargement or impotence in men <p>Eye disorders</p> <ul style="list-style-type: none"> ● blurred vision <p>Musculoskeletal and connective tissue disorders:</p> <ul style="list-style-type: none"> ● back pain <p>Vascular disorders:</p> <ul style="list-style-type: none"> ● high or low blood pressure <p>Injury, Poisoning and Procedural Complications:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> • falls <p>Investigations:</p> <ul style="list-style-type: none"> • weight gain 	

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 ARDIX LURASIDONE contains

Active ingredient (main ingredient)	lurasidone hydrochloride
Other ingredients (inactive ingredients)	carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry complete film coating system 03F48969 white, pregelatinised maize starch, colourings: indigo carmine and iron oxide yellow (80 mg tablet only)
Potential allergens	ARDIX LURASIDONE does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

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

What ARDIX LURASIDONE looks like

ARDIX LURASIDONE is registered on the Australian register of Therapeutic Goods and has the Australia Register numbers:

- AUST R 324800 – 40 mg tablets

- AUST R 324801 – 80 mg tablets

ARDIX LURASIDONE 40 mg tablets are round, white to off-white and debossed on one side with “L40”.

ARDIX LURASIDONE 80 mg tablets are oval-shaped, pale green and debossed on one side with “L80”.

ARDIX LURASIDONE tablets come in a blister strip. Each box contains 30 tablets.

Who distributes ARDIX LURASIDONE

ARDIX LURASIDONE is supplied in Australia by:

Servier Laboratories (Aust.) Pty. Ltd.

Level 4, Building 9,

588A Swan Street

Burnley, 3121, Victoria

Telephone: 1800 153 590

Internet: www.servier.com.au

This leaflet was prepared in November 2022.