

- ▼ 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

Lurasidone Hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ARDIX LURASIDONE.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ARDIX LURASIDONE against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What ARDIX LURASIDONE is used for

ARDIX LURASIDONE is used to treat adults and adolescents (aged 13 years or 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 belongs to a group of medicines called atypical antipsychotics. It helps to correct chemical imbalances in the brain, which may cause mental illness.

There is no evidence that ARDIX LURASIDONE is addictive or habit forming.

This medicine 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.

Before you use ARDIX LURASIDONE

When you must not take it

Do not take ARDIX LURASIDONE if:

- **you have an allergy to lurasidone hydrochloride (the active ingredient in ARDIX LURASIDONE) or any of the ingredients listed at the end of this leaflet.**
- **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.**

Do not take ARDIX LURASIDONE after the expiry date printed on the pack or the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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.

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.

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

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.

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

Tell your doctor if you have or have had any medical conditions, especially the following:

- 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
- 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
- disease of the blood with a reduced number of white blood cells (e.g. leukopenia or neutropenia)
- diabetes, increased blood sugar (also known as hyperglycaemia)
- 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)
- dyslipidemia (e.g. changed levels of lipids such as cholesterol, triglycerides etc. in the blood)

- 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 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)
- difficulty in 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.

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

Taking other medicines

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

Some medicines and ARDIX LURASIDONE may interfere with each other, these medicines are listed in the When you must not take it section above.

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.

How to take ARDIX LURASIDONE

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

They may differ from the information contained in this leaflet.

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

How much to take

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.

How to take it

Swallow ARDIX LURASIDONE whole with a glass of water. Do not chew the tablets.

When to take it

Take ARDIX LURASIDONE 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 long to take it

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 it

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 that 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ARDIX LURASIDONE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. If you take too much, you may experience:

- fast, slow or irregular heart beat
- low blood pressure (i.e. dizziness, lightheadedness)
- reduced alertness
- seizures (i.e. fits)
- uncontrolled muscle spasms affecting the head and neck.

While you are using ARDIX LURASIDONE

Things you must 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 heart beat, 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.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

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

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

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 any medicines that cause drowsiness while you are taking ARDIX LURASIDONE, unless recommended by your doctor.

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 drive or operate machinery 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARDIX LURASIDONE.

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

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

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

You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting
- diarrhoea, abdominal pain
- 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)
- sleepiness, difficulty sleeping
- indigestion
- increased saliva
- back pain
- dizziness
- decreased appetite
- blurred vision
- high blood pressure

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- **sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing**
- severe spasms in the muscles of the shoulders, neck and upper body
- temporary paralysis, weakness of muscles or muscle pain
- 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
- suicidal thoughts or behaviour
- seizure
- 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 a blood vessels).

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using ARDIX LURASIDONE

Storage

Keep your tablets in the pack until it is time to take them.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking ARDIX LURASIDONE or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

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.

Ingredients

Active ingredient:

- lurasidone hydrochloride

Other ingredients:

- carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, Opadry complete film coating system 03F48969 white, pregelatinised starch, colourings: indigo carmine and iron oxide yellow (80 mg tablet only).

ARDIX LURASIDONE does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

ARDIX LURASIDONE is supplied in Australia by:

Servier Laboratories (Aust.) Pty Ltd

8 Cato Street

PO Box 196

Hawthorn Victoria 3122.

Australian Registration Numbers:

AUST R 324800: 40 mg tablets

AUST R 324801: 80 mg tablets

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