

- ▼ 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 .

LAVIONE®

lurasidone hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LAVIONE. 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 LAVIONE 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 LAVIONE is used for

LAVIONE 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 LAVIONE for another reason. Ask your doctor if you have any questions about why LAVIONE has been prescribed for you.

LAVIONE 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 LAVIONE is addictive or habit forming.

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

LAVIONE 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.

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

Your doctor may have prescribed it for another reason.

When you must not take it

Do not take LAVIONE if you have an allergy to:

- any medicine containing lurasidone
- any of the ingredients listed at the end of this leaflet
- you are taking medicines that can affect how your body processes LAVIONE 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 (*hypericum perforatum*), used to treat depression.

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
- rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if 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 this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- 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)
- dyslipidaemia (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.

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

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

It is recommended that you do not breast-feed while taking LAVIONE, 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 LAVIONE.

If you have not told your doctor about any of the above, tell him/her before you start taking LAVIONE.

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 and LAVIONE 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 LAVIONE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take LAVIONE

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 the tablets whole with a full glass of water. Do not chew the tablets.

When to take it

Take your medicine during eating, or immediately after eating. Consider taking it after your evening meal.

Unless your doctor gives you other directions, you should take LAVIONE only once a day.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Therefore, you must take LAVIONE every day.

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 (Australia telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much LAVIONE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

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

While you are using LAVIONE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking LAVIONE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

- 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).

Keep all of your doctors' appointments so that your progress can be checked.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

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

Things to be careful of

Grapefruit and grapefruit juice should be avoided while taking LAVIONE.

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

Be careful driving or operating machinery until you know how LAVIONE affects you. Speak with your doctor about when you can resume these activities.

As with other antipsychotic medicines, LAVIONE has the potential to impair judgement, thinking or motor skills in some people. Make sure you know how you react to LAVIONE before you drive a car, operate machinery, or do anything else that could be dangerous if you are affected by LAVIONE.

Side effects

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

This medicine helps most people with schizophrenia, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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 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 vessel).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using LAVIONE

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store LAVIONE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

LAVIONE 40 mg: White to off white, round shaped, biconvex, film-coated tablets debossed with 516 on one side and L on other side.

LAVIONE 80 mg: Pale green oval shaped biconvex film-coated tablets debossed with L517 on one side and plain on other side.

Ingredients

LAVIONE contains either 40 mg or 80 mg of lurasidone hydrochloride as the active ingredient.

The tablets also contain the following inactive ingredients:

- croscarmellose sodium
- hypromellose
- magnesium stearate

- maize starch
- mannitol
- OPADRY complete film coating system 03F180011
White (40 mg only)
- OPADRY complete film coating system 03F510034
GREEN (80 mg only)

Sponsor

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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LAVIONE® is a Viatrix company trade mark

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