

## 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 taking LAVIONE?

LAVIONE contains the active ingredient lurasidone hydrochloride. LAVIONE 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 taking LAVIONE?](#) in the full CMI.

### 2. What should I know before I take LAVIONE?

Do not take if you have ever had an allergic reaction to lurasidone hydrochloride 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. LAVIONE 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 take LAVIONE?](#) in the full CMI.

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

Some medicines may interfere with LAVIONE 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 take LAVIONE?

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 LAVIONE only once a day. Take LAVIONE during or immediately after food, consider evening meal. More instructions can be found in Section [4. How do I take LAVIONE?](#) in the full CMI. **Continue taking the tablets for as long as your doctor tells you.**

### 5. What should I know while taking LAVIONE?

Things you should do	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using LAVIONE.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>Do not stop taking LAVIONE, or lower the dosage, even if you are feeling better, without checking with your doctor.</li><li>Do not take any other medications, whether they require a prescription or not, without telling your doctor you are taking LAVIONE as sometimes the action of one medicine may interfere with another.</li><li>Avoid grapefruit and grapefruit juice while taking LAVIONE.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>Do not drive or operate machinery until you know how LAVIONE affects you. Speak with your doctor about when you can resume these activities.</li></ul>
Drinking alcohol	<ul style="list-style-type: none"><li>Talk to your doctor about how much alcohol you drink. People who drink excessive quantities of alcohol should not take LAVIONE.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>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 25°C. Keep it where children cannot reach them.</li></ul>

For more information, see Section [5. What should I know while taking LAVIONE?](#) 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](http://www.tga.gov.au/reporting-problems).

# LAVIONE®

Active ingredient: *lurasidone hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking LAVIONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LAVIONE.**

Where to find information in this leaflet:

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

## 1. Why am I taking LAVIONE?

LAVIONE contains the active ingredient *lurasidone hydrochloride*.

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

**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.

There is no evidence that LAVIONE is addictive or habit forming.

LAVIONE is only available 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.

LAVIONE is not approved for the treatment of elderly patients with dementia-related psychosis or behavioural disorders. Medicines like LAVIONE can increase the risk of death in elderly people who have memory loss (dementia).

## 2. What should I know before I take LAVIONE?

There are some people who shouldn't take LAVIONE. 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 take LAVIONE if:

- you are allergic to *lurasidone hydrochloride*, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - o shortness of breath
  - o wheezing or difficulty breathing
  - o swelling of the face, lips, tongue or other parts of the body
  - o rash, itching or hives on the skin.

**Always check the ingredients to make sure you can take this medicine.**
- you are taking medicines that can affect how your body processes LAVIONE such as:
  - o ketoconazole or voriconazole, used to treat certain fungal infections
  - o ritonavir, used to treat HIV infection
  - o carbamazepine, used to treat convulsions (fits)
  - o phenytoin, used to treat convulsions (fits) and some heart conditions
  - o rifampicin or clarithromycin, used to treat bacterial infections
  - o herbal medicines derived from St. John's Wort (*hypericum perforatum*), used to treat depression.
- the expiry date (EXP) printed in the pack has passed or the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return to your pharmacist for safe disposal.
- If you are not sure whether you should start taking LAVIONE, talk to your doctor.

**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 LAVIONE.

**Check with your doctor if you have or have had any of the following medical conditions:**

- dementia-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 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.**

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, 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.

Newborn babies exposed to antipsychotic medicines (including LAVIONE) 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 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.

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

## **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 LAVIONE and affect how it works. Medicines can affect how your body processes LAVIONE 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 (*hypericum perforatum*), used to treat depression.

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.

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

## **4. How do I 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.

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

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

### When to take LAVIONE

- LAVIONE should be taken 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 to take LAVIONE

Swallow LAVIONE whole with a glass of water. Do not chew the tablets. Continue taking your medicine for as long as your doctor tells you.

This medicine helps 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 LAVIONE

LAVIONE should be taken 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 LAVIONE 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 LAVIONE

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

If you think that you or anyone else has taken too much LAVIONE, urgent medical attention may be needed.

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

**You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

- If anyone accidentally swallows any of your LAVIONE 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 taking LAVIONE?

### Things you should do

- If you are about to be started on any new medicines, remind your doctor and pharmacist that you are taking LAVIONE.
- **Tell any other doctors, dentists, and pharmacists who treat you that you are taking LAVIONE, if:**
  - o you have signs of frequent infections such as fever, chills, sore throat or mouth ulcers
  - o you have hyperglycaemia (high blood sugar)
  - o 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')
  - o dizziness on standing up, especially when getting up from a sitting or lying position (orthostatic hypotension) or fainting
  - o 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).

- If you plan to have surgery that needs a general anaesthetic, 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 LAVIONE, tell your doctor immediately.
- If you are about to have any medical tests while you are taking LAVIONE, tell your doctor that you are taking this medicine.

LAVIONE 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 LAVIONE 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 LAVIONE. Grapefruit and grapefruit juice may affect the amount of LAVIONE in your blood.

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

#### Call your doctor straight away 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.

- **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 taking LAVIONE.

#### Things you should not do

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

If you stop taking LAVIONE suddenly, your condition may worsen or you may have unwanted side effects.

To prevent this, your doctor may gradually reduce the amount of LAVIONE you take each day before stopping completely.
- **Do not take LAVIONE to treat any other complaints unless your doctor tells you to.**
- **Do not take any medicines that cause drowsiness while you are taking LAVIONE, unless recommended by your doctor.**
- **You should not take LAVIONE together with certain medications (see also under "Do not take LAVIONE if") as they can affect how your body processes LAVIONE.**
- **Do not give LAVIONE to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.**

#### 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.

- Do not become too hot or dehydrated while taking LAVIONE 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 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.

#### 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 LAVIONE.

#### Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take your tablets out of the pack they may not keep well.
- Store below 25°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; for example, do not store it:

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

Heat or dampness may destroy some medicines,

**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.

#### When to discard your medicine

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 take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take 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.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

### Serious side effects

Serious side effects	What to do
<p><b>Severe allergic reaction exists with any medication. The following are general signs and symptoms of an allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• skin rash, itching or hives</li> <li>• swelling of the face, lips, tongue or other parts of the body</li> <li>• shortness of breath, wheezing or difficulty breathing</li> </ul> <p><b>Musculoskeletal and connective tissue disorders:</b></p> <ul style="list-style-type: none"> <li>• temporary paralysis, weakness of muscles or muscle pain</li> <li>• severe spasms in the muscles of the shoulders, neck and upper body</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• 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</li> <li>• 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</li> </ul> <p><b>Psychiatric disorders:</b></p> <ul style="list-style-type: none"> <li>• suicide thoughts or behaviour</li> </ul> <p><b>Vascular disorders:</b></p> <ul style="list-style-type: none"> <li>• stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death</li> <li>• 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)</li> </ul> <p><b>Blood and lymphatic system disorders:</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>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>

### Less serious side effects

Less serious side effects	What to do
<p><b>Psychiatric disorders:</b></p> <ul style="list-style-type: none"> <li>• restlessness, agitation, anxiety</li> <li>• 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)</li> </ul> <p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• sleepiness (somnolence), difficulty sleeping (insomnia)</li> </ul> <p><b>Gastrointestinal disorders:</b></p> <ul style="list-style-type: none"> <li>• feeling sick (nausea), vomiting</li> <li>• diarrhoea, abdominal pain</li> <li>• indigestion</li> <li>• decreased appetite</li> <li>• increased saliva</li> <li>• difficulty swallowing</li> </ul> <p><b>Reproductive system and breast disorders:</b></p> <ul style="list-style-type: none"> <li>• breast swelling, unusual secretion of breast milk, missed or irregular menstrual periods. Breast enlargement or impotence in men.</li> </ul> <p><b>Eye disorders:</b></p> <ul style="list-style-type: none"> <li>• blurred vision</li> </ul> <p><b>Musculoskeletal and connective tissue disorders:</b></p> <ul style="list-style-type: none"> <li>• back pain</li> </ul> <p><b>Vascular disorders:</b></p> <ul style="list-style-type: none"> <li>• high or low blood pressure</li> </ul> <p><b>Injury, Poisoning and Procedural Complications:</b></p> <ul style="list-style-type: none"> <li>• falls</li> </ul> <p><b>Investigations:</b></p> <ul style="list-style-type: none"> <li>• weight gain</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

**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](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.**

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## 7. Product details

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

### What LAVIONE contains

<b>Active ingredient (main ingredient)</b>	lurasidone hydrochloride 40 or 80 mg per tablet
<b>Other ingredients (inactive ingredients)</b>	croscarmellose sodium hypromellose magnesium stearate maize starch mannitol  OPADRY complete film coating system 03F180011 White (PI No: 114103) (40 mg only)  OPADRY complete film coating system 03F510034 GREEN (PI No: 116683) (80 mg only)

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

### What LAVIONE looks like

LAVIONE 40 mg tablets are white to off white, round shaped, biconvex, film-coated tablets debossed with 516 on one side and L on other side. (AUST R 321652).

LAVIONE 80 mg tablets are pale green, oval shaped, biconvex, film-coated tablets debossed with L517 on one side and plain on other side. (AUST R 321653).

Available in blister packs of 30 tablets.

### Who distributes LAVIONE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in August 2024.

LAVIONE® is a Viatris company trade mark