

LURASIDONE SUN

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 LURASIDONE SUN?

LURASIDONE SUN contains the active ingredient lurasidone hydrochloride. LURASIDONE SUN is used to treat adults and adolescents (aged 13 years or over) with schizophrenia.

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

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

Do not use 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.

For more information, see Section [2. What should I know before I use LURASIDONE SUN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LURASIDONE SUN 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 LURASIDONE SUN?

- Your doctor or pharmacist will tell you how many tablets you will need to take each day.
- Take LURASIDONE SUN during or immediately after food, consider evening meal.

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

5. What should I know while using LURASIDONE SUN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using lurasidone hydrochloride.• Be sure to keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or lower the dosage suddenly.• Unless recommended, do not take any medicines that cause drowsiness.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how LURASIDONE SUN affects you. Speak with your doctor about when you can resume these activities.
Drinking alcohol	<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 LURASIDONE SUN.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C in a cool dry place.

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

6. Are there any side effects?

- Common: nausea, vomiting, diarrhoea, abdominal pain, restlessness, agitation, anxiety, extrapyramidal symptoms, sleepiness, difficulty sleeping, indigestion, increased saliva, back pain, dizziness, decreased appetite, blurred vision, high blood pressure.
- Serious: allergy, severe muscle spasms, temporary paralysis, uncontrolled movements of the tongue/mouth/cheeks/jaw, suicidal thoughts/behavior, seizure, symptoms associated with blockage in a blood vessel.

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.

LURASIDONE SUN

Lurasidone hydrochloride (s): [medicine active ingredient(s)]

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using LURASIDONE SUN?

LURASIDONE SUN contains the active ingredient lurasidone hydrochloride. LURASIDONE SUN is an atypical antipsychotic. It helps to correct chemical imbalances in the brain, which may cause mental illness.

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

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

Warnings

Do not use LURASIDONE SUN 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 LURASIDONE SUN 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.
- if LURASIDONE SUN is expired (check 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.

Check with your doctor if you:

- have any other 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.
- take any medicines for any other condition
- have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

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.

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

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

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

Use in children or adolescents

- LURASIDONE SUN 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.

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 LURASIDONE SUN and affect how it works.

Medicines that can affect how your body processes LURASIDONE SUN 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.

These medicines may be affected by LURASIDONE SUN, 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 LURASIDONE SUN.

4. How do I use LURASIDONE SUN?

How much to take / use

- 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.
- Follow the instructions provided and use LURASIDONE SUN until your doctor tells you to stop.
- Continue taking the tablets for as long as your doctor tells you. LURASIDONE SUN helps control your condition, but does not cure it. Therefore you must take LURASIDONE SUN every day. Do not stop taking it unless your doctor tells you to - even if you feel better.

When to take / use LURASIDONE SUN

- LURASIDONE SUN should be taken during or immediately after food, consider your evening meal.
- Unless your doctor gives you other directions, you should take LURASIDONE SUN only once a day.

How to take LURASIDONE SUN

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

If you forget to use LURASIDONE SUN

LURASIDONE SUN should be used regularly at the same time each day.

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.

If you use too much LURASIDONE SUN

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

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.

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.

5. What should I know while using LURASIDONE SUN?

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking LURASIDONE SUN 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 LURASIDONE SUN
- you need to have any medical tests while you are taking LURASIDONE SUN
- 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).

LURASIDONE SUN may affect the results of some tests.

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

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

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage, even if you are feeling better, without checking with your doctor.
 - If you stop taking LURASIDONE SUN 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 LURASIDONE SUN you take each day before stopping completely.
- Do not give LURASIDONE SUN to anyone else, even if their symptoms seem similar or they have the same condition as you.
- Do not take LURASIDONE SUN to treat any other complaints unless your doctor tells you to.
- Do not take any medicines that cause drowsiness while you are taking LURASIDONE SUN, unless recommended by your doctor.
- Grapefruit and grapefruit juice should be avoided while taking LURASIDONE SUN.
 - Grapefruit juice contains one or more components that alter the metabolism of some medicines, including LURASIDONE SUN. This may lead to higher and unpredictable levels of lurasidone in the blood.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LURASIDONE SUN affects you.

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

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 LURASIDONE SUN.].

Looking after your medicine

- Store below 30°C.
- Keep your tablets in the pack until it is time to take them.

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.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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	<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>

may progress to the arms and legs	
<ul style="list-style-type: none">• 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)	

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 LURASIDONE SUN contains

Active ingredient (main ingredient)	lurasidone hydrochloride
Other ingredients (inactive ingredients)	Mannitol, Alginic Acid, Pregelatinized starch, Croscarmellose Sodium, Purified Water, Colloidal Silicon Dioxide, Magnesium Stearate, Opadry complete film coating system 03B580015 White (ARTG PI No. 138475) (20 mg and 40 mg tablets), Opadry complete film coating system 03B510036 Green (ARTG PI No. 138474) (80 mg tablet)

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

What LURASIDONE SUN looks like

Lurasidone SUN 20mg: White to off-white, round, film-coated tablet, debossed with '578' on one side and plain on other side (Aust R 330270)

Lurasidone SUN 40mg: White to off-white, round, film-coated tablet, debossed with '684' on one side and plain on other side (Aust R 330268)

Lurasidone SUN 80mg: Pale green coloured, oval shaped, film-coated tablet, debossed with '685' on one side and plain on other side (Aust R 330269)

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

Who distributes LURASIDONE SUN

Sun Pharma ANZ Pty Ltd

12 Waterloo Road

Macquarie Park, NSW 2113

Australia

Email: customerservice.aus@sunpharma.com

Tel. No. 1800 726 229

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