

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking LUMIN?

LUMIN contains the active ingredient mianserin (hydrochloride). LUMIN is used to treat depression.

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

2. What should I know before I take LUMIN?

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

3. What if I am taking other medicines?

Some medicines may interfere with LUMIN 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 LUMIN?

- Your doctor will tell you how much LUMIN to take each day. Take exactly the amount your doctor tells you to.
- The dose varies from patient to patient.

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

5. What should I know while taking LUMIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking LUMIN. • Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes. • Tell your doctor immediately if you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections.
Things you should not do	• Do not suddenly stop taking LUMIN or lower the dose without first checking with your doctor. • Do not stop taking LUMIN even if you feel better unless advised by your doctor. • Do not give LUMIN to anyone else, even if they have the same condition as you.
Driving or using machines	• Do not drive or operate machinery until you know how LUMIN affects you. • LUMIN may cause drowsiness, dizziness, lightheadedness, sleepiness or affect concentration in some people.
Drinking alcohol	• Do not drink alcohol while taking LUMIN. • Combining alcohol with LUMIN can make you more drowsy, dizzy or lightheaded.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 30°C. • Keep LUMIN where children cannot reach it.

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

6. Are there any side effects?

Less serious side effects: constipation, weight gain, tiredness, dizziness on standing up, impotence or nasal congestion. **Serious side effects:** skin rash, painful, swollen joints, vision problems, unusual changes in behaviour or sudden switch of mood to one of excitement, overactivity and talkativeness. **Very serious side effects:** having thoughts of harming or killing yourself, bruising or bleeding more easily than normal, stiffness in the body, involuntary movements, extremely high blood pressure, changes to heart rhythm, chest pain, yellowing of the eyes or skin (jaundice) and fits or convulsions. **Please note this is not a complete list of side effects.**

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking LUMIN. **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 LUMIN.**

Where to find information in this leaflet:

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

1. Why am I taking LUMIN?

LUMIN contains the active ingredient **mianserin (hydrochloride)**. LUMIN is an antidepressant, which works by acting on chemicals in your brain called amines. These amines are involved in controlling your mood.

LUMIN is used to treat depression.

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

2. What should I know before I take LUMIN?

Warnings

Do not take LUMIN if:

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

Always check the ingredients to make sure you can take this medicine.

- you suffer from mania, a mental condition characterised by episodes of overactivity, elation or irritability
- you have severe liver disease
- **you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI), or have been taking a MAOI within the last 14 days. If you stop taking LUMIN, do not take MAOI during the next 2 weeks either.**

Taking LUMIN with an MAOI may cause a serious reaction with a sudden increase in body temperature,

extremely high blood pressure and severe convulsions.

Ask your doctor or pharmacist if you are not sure if you are taking, or have been taking a MAOI. MAOIs are medicines used to treat depression and symptoms of Parkinson's disease. Examples of MAOIs are phenelzine, tranylcypromine, moclobemide, selegiline and linezolid.

- the packaging shows signs of tampering or the tablets do not look quite right
- the expiry date printed on the pack has passed.

If you take this medicine after the expiry date it may not work as well.

Talk to your doctor if you are not sure whether you should start taking this medicine.

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- take any medicines for any other condition
- have or have had any of the following medical conditions:
 - o blood pressure problems
 - o heart disease, including certain kinds of heart conditions that change your heart rhythm, a recent heart attack, heart failure, or taking certain medicines known to change heart rhythm
 - o liver problems (e.g. jaundice)
 - o kidney problems
 - o any mental illness other than depression
 - o epilepsy, (fits or convulsions)
 - o diabetes
 - o glaucoma, (increased pressure in the eye)
 - o problems with urinating due to an enlarged prostate
 - o mental illness such as schizophrenia and manic depression (alternating periods of elation/overactivity and depressed mood).

If you have not told your doctor about any of the above, tell them before you start taking LUMIN.

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 plan to become pregnant.

Your doctor will discuss the risks and benefits of taking LUMIN during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

It is not known whether LUMIN passes into breast milk. Your doctor will discuss the risks and benefits of taking LUMIN when breastfeeding.

Use in children or adolescents

LUMIN is not approved for use in children and adolescents below 18 years of age for the treatment of depression or other mental disorders.

The safe use and effectiveness of LUMIN in treating these disorders, for this age group, has not been established.

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.

Do not take LUMIN if you are taking any monoamine oxidase inhibitor (MAOI) such as:

- phenelzine, tranylcypromine or moclobemide, used to treat depression
- selegiline, used to treat symptoms of Parkinson's disease.

Wait at least 14 days after stopping your MAOI before starting LUMIN.

Some medicines may interfere with LUMIN and affect how it works. These include:

- other medicines for depression
- Monoamine Oxidase Inhibitors (MAOIs)
- medicines used to treat epilepsy such as barbiturates, carbamazepine and phenytoin
- medicines used to treat high blood pressure
- oral antidiabetic medicines or insulin
- medicines used to prevent blood clots, such as warfarin
- medicines that may affect the heart rhythm such as certain antibiotics and some antipsychotics.

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

Your doctor can tell you what to do if you are taking any of these medicines.

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

4. How do I take LUMIN?

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

- **Your doctor will tell you how much LUMIN to take each day. Take exactly the amount your doctor tells you to.**
- The dose varies from patient to patient.
- Your doctor will decide the right dose for you. This depends on your condition, age, whether or not you are taking any other medicines, and how you respond to LUMIN.
- LUMIN is usually started at a low dose, at 30 mg per day. This may be given as a single night-time dose before going to bed or given in three divided doses. Your doctor may slowly increase this dose depending on how you respond to LUMIN. The effective dose for most people is usually between 30 mg and 90 mg per day.

Elderly:

- The usual starting dose will not be more than 30 mg per day. Your doctor may slowly increase or decrease your dose, depending on how you respond to LUMIN.

How to take LUMIN

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

When to take LUMIN

- LUMIN should be taken between meals.
- LUMIN can be taken as a single dose (e.g. at bedtime) or as divided doses (e.g. three times a day). Your doctor will advise you.
- **Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you to remember when to take it.

How long to take LUMIN for

- Keep taking LUMIN for as long as your doctor recommends.
- The length of treatment will depend on how quickly your symptoms improve.
- Most medicines for depression take some time to work, so do not be discouraged if you do not feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel the full benefit of LUMIN.
- Even when you feel well, you will usually have to take LUMIN for several months or longer, to make sure the benefits will last.

If you forget to take LUMIN

If you take one dose a day at bedtime:

If you forget to take LUMIN before you go to bed and you wake up late in the night or early in the morning, do not take any LUMIN until you have checked with your doctor.

You may have difficulty waking up or experience drowsiness in the morning or during the day, if you take LUMIN at these times.

If you take more than one dose a 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.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much LUMIN

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

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.

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

If you take too much LUMIN, you may feel drowsy, dizzy and lightheaded have changes in heart rate (fast, slow or irregular), and/or fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes. You may also have fits and problems breathing.

Keep LUMIN out of reach of children.

Children are much more sensitive than adults to medicines such as LUMIN. An accidental overdose is especially dangerous.

5. What should I know while taking LUMIN?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking LUMIN.
- Tell all the doctors, dentists and pharmacists who treat you that you are taking this medicine.
- 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 that LUMIN is not helping your condition.
- Keep all of your appointments with your doctor so that your progress can be checked.
- You may need to have blood tests from time to time.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

Call your doctor or a mental health professional right away or go to the nearest hospital for

treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Call your doctor straight away if you:

- have any suicidal thoughts or other mental/mood changes

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent.

Information from clinical trials have shown an increased risk of suicidal behaviour in young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

- develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections

In rare cases, LUMIN can cause a shortage of white blood cells, resulting in the lowering of the body resistance to infection. These symptoms may appear after 4-6 weeks of treatment.

- become pregnant while taking LUMIN. Do not stop taking your tablets until you have spoken to your doctor.

Things you should not do

- **Do not suddenly stop taking LUMIN or lower the dose without first checking with your doctor. Do not let yourself run out of tablets over the weekend or on holidays.**

If you suddenly stop taking LUMIN, you may feel unwell, sick in the stomach or have a headache.

Your doctor will tell you how to gradually reduce the amount of LUMIN you are taking before stopping completely.

- Do not stop taking LUMIN even if you feel better unless advised by your doctor.
- Do not use LUMIN to treat any other conditions unless your doctor tells you to.
- Do not give LUMIN to anyone else, even if they have the same condition as you.

Driving or using machines

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

LUMIN may cause drowsiness, dizziness, lightheadedness, sleepiness or affect concentration in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while taking LUMIN.

Combining alcohol with LUMIN can make you more drowsy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while being treated with LUMIN.

Looking after your medicine

- Store below 30°C.

Follow the instructions on 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 and dampness can 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.

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.

Medicines should not be disposed of via wastewater or household waste. These measures will help protect the environment.

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 LUMIN.

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

Don't be alarmed by this possible list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Ear-related: • ringing or persistent noise in ears	Speak to your doctor if you have any of these less

Less serious side effects	What to do
Gastrointestinal-related: • constipation • dry mouth • weight gain Liver-related: • hepatitis (inflammation of the liver) Nervous system-related: • dizziness, faintness • headache • restless legs • tiredness, drowsiness or lack of energy • tremor • weakness Reproductive system-related: • breast enlargement in men • impotence Respiratory-related: • nasal congestion Vascular system-related: • dizziness on standing up, especially when getting up from a sitting or lying down position	serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Musculoskeletal-related: • aching muscles, muscle tenderness or weakness, not caused by exercise • painful, swollen joints Nervous system-related: • tingling or numbness of the hands or feet Psychiatric-related: • confusion, agitation, irritability, hostility (aggressiveness), unusual changes in behaviour • sudden switch of mood to one of excitement, overactivity, talkativeness and uninhibited behaviour Skin-related: • itching • skin rash Vision-related: • vision problems	Call your doctor straight away if you notice any of these serious side effects.

Very serious side effects

Very serious side effects	What to do
Bleeding-related: - bruising or bleeding more easily than normal, nosebleeds Cardiovascular system-related: - changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes - chest pain - shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet or legs due to fluid build up - slow heart beat Immune system-related: - signs of frequent infections such as fever, chills, sore throat or mouth ulcers Liver-related: - yellowing of the eyes or skin (jaundice) Nervous system-related: - fits or convulsions - stiffness in the body, involuntary movements, a sudden increase in body temperature, extremely high blood pressure and severe convulsions (Neuroleptic Malignant Syndrome) - tiredness, headaches, being short of breath when exercising Psychiatric-related: - having thoughts of harming or killing yourself	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.

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 LUMIN contains

Active ingredient (main ingredient)	mianserin 10 mg or 20 mg per tablet
Other ingredients (inactive ingredients)	- pregelatinised maize starch - colloidal anhydrous silica - microcrystalline cellulose - calcium hydrogen phosphate - magnesium stearate - carnauba wax - Opadry Complete film coating system White Y-1-7000 (ID: 1475).
Potential allergens	trace quantities of sulfites

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

What LUMIN looks like

LUMIN 10 - 6 mm normal convex white film coated tablet marked MI 10 on one side, G on reverse. (AUST R 55272).

LUMIN 20 - 7 mm normal convex white film coated tablet marked MI 20 on one side, G on reverse. (AUST R 55273).

Each pack contains 50 tablets.

Who distributes LUMIN

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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