Lumin

mianserin (hydrochloride)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Lumin.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Lumin against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Lumin is used for

Lumin is used to treat depression.

Lumin is an antidepressant, which works by acting on chemicals in your brain called amines. These amines are involved in controlling mood.

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.

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.

Lumin is available only with a doctor's prescription.

Before you take Lumin

When you must not take it

Do not take Lumin if you are allergic to:

- medicines containing mianserin hydrochloride (e.g. Tolvon)
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or troubled breathing.

Check with your doctor or pharmacist if you are not sure about any of the above.

Do not take Lumin if you:

- suffer from mania, a mental condition characterised by episodes of overactivity, elation or irritability.
- have severe liver disease

Do not take Lumin if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI), or have been taking an 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 (Nardil), tranylcypromine (Parnate), moclobemide (e.g. Aurorix, Arima), selegiline (Eldepryl, Selgene) and linezolid (Zyvox).

Do not take Lumin if the packaging shows signs of tampering or the tablets do not look quite right.

Do not take Lumin if the expiry date (EXP) 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.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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.

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

- blood pressure problems
- 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
- liver problems (e.g. jaundice)
- kidney problems
- any mental illness other than depression
- epilepsy, (fits or convulsions)
- diabetes
- glaucoma, (increased pressure in the eye)
- problems with urinating due to an enlarged prostate.
- 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 him/ her before you start taking Lumin.

Taking other medicines

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

- phenelzine (Nardil) and tranylcypromine (Parnate), moclobemide (eg. Aurorix, Arima), used to treat depression
- selegiline (Eldepryl, Selgene), used to treat symptoms of Parkinson's disease.

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

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

Some medicines may be affected by Lumin or may affect how well 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 anti-psychotics.

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

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to 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 30mg 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 30mg and 90mg per day.

Elderly:

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

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

How to take it

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

When to take it

Lumin should be taken between meals.

Lumin can be taken as a single dose (eg. at bedtime) or as divided doses (eg. 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 remember when to take it.

How long to take it 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 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 it

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Lumin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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 the reach of children.

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

While you are taking Lumin

Things you must 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 immediately 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.

Contact 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.

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 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.

Tell your doctor immediately if you 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.

Tell your doctor immediately if you become pregnant while taking Lumin. Do not stop taking your tablets until you have spoken to your doctor.

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

Things you must not do

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. If any of these occur, do not drive, operate machinery or do

anything else that could be dangerous.

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.

Things to be careful of

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.

Side effects

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

Lumin helps most people with depression, but it may have unwanted side effects in some people.

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 if you notice any of the following and they worry you:

- tiredness, drowsiness or lack of energy
- dry mouth
- dizziness on standing up, especially when getting up from a sitting or lying down position
- dizziness, faintness
- weakness
- tremor
- headache
- dry mouth
- constipation
- weight gain
- impotence
- breast enlargement in men
- restless legs
- ringing or persistent noise in the ears
- nasal congestion
- hepatitis (inflammation of the liver)

Tell your doctor as soon as possible if you notice any of the following:

- skin rash
- itching
- vision problems
- tingling or numbness of the hands or feet
- painful, swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise
- sudden switch of mood to one of excitement, overactivity, talkativeness and uninhibited behaviour
- confusion, agitation, irritability, hostility (aggressiveness), unusual changes in behaviour.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- you have thoughts of harming or killing yourself
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal, nosebleeds
- tiredness, headaches, being short of breath when exercising
- fits or convulsions
- yellowing of the eyes or skin (jaundice)
- slow heart beat
- 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
- stiffness in the body, involuntary movements, a sudden increase in body temperature, extremely high blood pressure and severe convulsions (Neuroleptic Malignant Syndrome).

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

Other side effects not listed above may also occur in some people.

After using Lumin

Storage

Keep Lumin where children cannot reach it.

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

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

Do not store Lumin or any other medicine in the bathroom or near a sink.

Do not leave Lumin in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

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

Product description

What it looks like

Lumin is available in 2 strengths:

- Lumin 10 - round, white tablet, marked "MI 10" on one side and "G" on the other side
- Lumin 20 - round, white tablet, marked "MI 20" on one side and "G" on the other side.

Each pack contains 50 tablets.

Ingredients

The active ingredient in Lumin is mianserin (as mianserin hydrochloride):

- each Lumin 10 tablet contains 10 mg of mianserin hydrochloride
- each Lumin 20 tablet contains 20 mg of mianserin hydrochloride.

The tablets also contain:

- pregelatinised maize starch
- colloidal anhydrous silica
- microcrystalline cellulose
- calcium hydrogen phosphate
- magnesium stearate
- carnauba wax
- Opadry White Y-1-7000 (contains colour 171).

Lumin tablets contain trace amounts of sulfites. Lumin tablets are gluten free.

Supplier

Lumin is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Lumin 10 - AUST R 55272

Lumin 20 - AUST R 55273

This leaflet was prepared on

20 December 2019.

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