

AGOMELATINE LUPIN

(agomelatine (as citric acid co-crystal)) film-coated tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Agomelatine Lupin.

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 Agomelatine Lupin against the benefits they expect it will have 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 Agomelatine Lupin is used for

Agomelatine Lupin is used in the treatment of depression or to help prevent depression returning, and is only available with a doctor's prescription. The symptoms of depression vary from one person to another, but commonly include persistent sadness, loss of interest in favourite activities, feelings of worthlessness, sleep problems, feeling of being slowed down, feelings of anxiety or changes in appetite and weight. Changes in your daily sleep and appetite patterns are examples of disturbances of your 'body clock' that occur commonly in depression.

Agomelatine Lupin can help regulate your 'body clock' (circadian rhythm) with positive benefits on mood and sleep in depression.

Agomelatine Lupin is not addictive. In clinical studies Agomelatine Lupin had no effect on sexual function. Agomelatine Lupin is not recommended for children, adolescents (under 18 years old) or elderly patients aged 75 or older.

Your doctor may prescribe Agomelatine Lupin for another purpose. Ask your doctor if you have any questions about why Agomelatine Lupin has been prescribed for you.

Before you take Agomelatine Lupin

There are some people who shouldn't take Agomelatine Lupin. Please read the list below. If you think any of these situations apply to you or you have any questions, please see your doctor.

When you must not take it

Do not take Agomelatine Lupin if:

- you suffer from liver disease or you know your liver does not work properly (hepatic impairment);
- routine blood tests show levels of liver enzymes have increased to more than 3 times the upper limit of normal;
- you are currently taking fluvoxamine (a drug used in the treatment of depression) or ciprofloxacin (an antibiotic used to treat infections);
- you have an allergy to Agomelatine Lupin or any of the ingredients (including lactose) listed at the end of this leaflet.

Do not take Agomelatine Lupin if the expiry date (Exp.) printed on the pack has passed.

Do not take Agomelatine Lupin if the packaging is torn or shows signs of tampering.

Before you start to take it

A routine blood test should be performed before treatment to check how your liver is functioning. If you have increased levels of

liver enzymes your doctor will decide if Agomelatine Lupin is right for you.

You may be at risk of liver problems if you are overweight, obese or have diabetes or if you are taking medicines known to affect your liver (ask your doctor if you are unsure which medicines these might be).

Tell your doctor if you have ever experienced or develop an episode of bipolar disorder, mania or hypomania (extreme upward mood swings or irritable mood).

Your doctor should be made aware if you have a history of dementia.

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

Talk to your doctor about how much alcohol you drink. People who drink excessive quantities of alcohol should not take Agomelatine Lupin. Excessive alcohol may cause liver problems and may make depression worse.

Tell your doctor if you are smoking more than 15 cigarettes/day.

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

Taking other medicines

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

Tell your doctor if you are taking propranolol (a medicine sometimes used to treat heart problems.)

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 Agomelatine Lupin.

How to take Agomelatine Lupin

Always take Agomelatine Lupin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow Agomelatine Lupin tablets whole with some water in the evening at bedtime.

Agomelatine Lupin can be taken with or without food.

How much to take

The usual dose of Agomelatine Lupin is one tablet in the evening at bedtime. In some cases your doctor may prescribe two tablets (50 mg) to be taken together in the evening at bedtime. You should not take more than the maximum recommended dose of 50 mg daily.

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

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

How long to take Agomelatine Lupin for

Current experience with medications to treat depression shows that treatment for six months or longer provides the best opportunity of long-term recovery from a first episode of depression. For those who have previously had depression, a longer period of treatment will usually be recommended.

With Agomelatine Lupin, some people experience improvements in mood and sleep within two weeks of starting treatment. As people respond differently to medications, do not become discouraged if you do not notice a difference right away.

Continue taking Agomelatine Lupin until your doctor advises you to stop. Even when you are feeling better, your doctor would usually continue to give you Agomelatine Lupin for some time to help to prevent your depression from returning.

If you forget to take it

If you forget to take your Agomelatine Lupin skip the dose you missed, take your next planned dose at the usual time and continue as normal.

To avoid confusion, it is recommended that you leave the tablet you missed in the tablet strip and continue on with the next day's tablet.

Do not try to make up for missed doses. Simply take one dose per day.

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), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Agomelatine Lupin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

The experience of overdoses with Agomelatine Lupin is limited but reported symptoms include stomach pain, drowsiness, tiredness, agitation, anxiety, dizziness, blue-ish discolouration of the skin or mucous membranes and/or a general feeling of being unwell.

If you do take more than you have been prescribed, contact your doctor immediately for advice.

If anyone accidentally swallows any of your Agomelatine Lupin tablets, **immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26). Do this even if there are no signs of discomfort or poisoning.**

While you are taking Agomelatine Lupin

Your liver function

Agomelatine Lupin is processed by the liver. Before you started taking Agomelatine Lupin a blood test was required to check your liver function. While you are taking Agomelatine Lupin you will need further blood tests to check your liver continues to function properly.

These tests should be performed:

- before the start of treatment and before a dose increase to 50 mg (dose should only be increased by your doctor);

and then around:

- 3 weeks,
- 6 weeks,
- 12 weeks, and
- 24 weeks.

These blood test results will help your doctor decide whether Agomelatine Lupin is suitable for you.

Agomelatine Lupin may sometimes affect the results of these blood tests.

You may also have tests to check that your liver is working properly if you start to take medicines that interfere with how the body processes Agomelatine Lupin.

Talk to your doctor about how much alcohol you drink.

Things you must do

To make sure you have the best opportunity of long-term recovery from your depression, continue to take Agomelatine Lupin as long as your doctor recommends you to.

Tell your doctor if you have experienced or develop an episode of bipolar disorder, mania or hypomania (extreme upward mood swings or irritable mood).

Check with your doctor that your liver function tests are done as described in the “Your Liver Function” section above.

Seek advice from your doctor immediately if you develop signs or symptoms of potential liver problems (such as dark urine, light coloured faeces, yellow skin or eyes, pain in your upper right abdomen, new-onset and unexplained fatigue). Your doctor may advise you to stop taking Agomelatine Lupin.

Tell your doctor immediately if you become pregnant while taking Agomelatine Lupin.

Tell all doctors, dentists and healthcare professionals who are treating you that you are taking Agomelatine Lupin.

Do not take any other medications, whether they require a prescription or not, without first telling your doctor that you are taking Agomelatine Lupin 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.

Keep all of your doctor’s appointments so that your progress can be checked.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

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. Such thoughts may even occur after commencing antidepressant treatment, particularly before the full antidepressant effect is seen. Such thoughts are more likely to occur in young adults under 25 years of age.

If you 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 of your depression;
- 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.

In addition to talking to your doctor, confidential support and counselling services are available (in Australia) from LifeLine by calling 13 11 14.

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

Things you must not do

You should not take Agomelatine Lupin together with certain medications (see also the “When you must not take it” section) such as: fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).

Do not give this medicine to anyone else even if their symptoms seem similar to yours or if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Agomelatine Lupin affects you.

Speak to your doctor if you have any concerns.

It is recommended to avoid drinking alcohol while taking any antidepressant including Agomelatine Lupin.

Side effects and unwanted effects potentially due to treatment and/or your depression

Tell your doctor or pharmacist or go to the nearest hospital as soon as possible if you do not feel well while you are taking Agomelatine Lupin.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

The possibility of a severe liver reaction exists, especially with excessive alcohol consumption and/ or with any other medication processed by the liver, eg. Agomelatine Lupin. Symptoms of severe liver reactions may include:

- yellow colouring of the skin or whites of the eyes (jaundice);
- abnormal bleeding or bruising;
- confusion, loss of consciousness or hallucinations.

The possibility of a severe allergic reaction exists with any medication. The following are general signs and symptoms of an allergic reaction:

- itching, skin rash or hives;
- shortness of breath, wheezing or trouble breathing;
- swelling of the face, lips, tongue or other parts of the body which may cause difficulty in swallowing or breathing.

Severe liver reactions and severe allergic reactions are very serious. Medical attention or hospitalisation may be required and should be sought urgently from a doctor or Accident and Emergency at the nearest hospital.

Agomelatine Lupin has been developed to treat people with depression and is usually well tolerated, however all medications may have unwanted effects in some people.

Increases in liver enzymes, and rarely inflammation of the liver, have been observed in

some patients treated with Agomelatine Lupin. When Agomelatine Lupin was discontinued in these patients, the increases in liver enzymes usually returned to normal levels. This is why your doctor has asked you to have routine blood tests.

Some people taking Agomelatine Lupin for depression have reported the following adverse reactions, which may relate to their depression, general health or any of their treatments.

Very common side effects (may affect more than 1 in 10 people):

- headache.

Common side effects (may affect up to 1 in 10 people):

- sleepiness (somnolence), difficulty in sleeping (insomnia);
- dizziness, abnormal dreams;
- feeling sick (nausea), diarrhoea, constipation, abdominal pain, vomiting;
- back pain;
- tiredness;
- anxiety;
- increased level of liver enzymes in your blood;
- weight increase.

Uncommon side effects (may affect up to 1 in 100 people):

- mania/hypomania (see also “Before you start to take it” section);
- suicidal thoughts or behaviour;
- pins and needles in the fingers and toes (paraesthesia), restless legs syndrome (a disorder that is characterised by an uncontrollable urge to move the legs);
- blurred vision;
- ringing in the ears;
- eczema, pruritus, urticarial (hives);
- agitation, irritability, restlessness, aggressive behaviour;
- nightmares;
- confusion;
- weight decrease;
- migraine;
- excessive sweating (hyperhidrosis).

Rare side effects (may affect up to 1 in 1,000 people):

- serious skin eruption (erythematous rash), face oedema (swelling) and angioedema (swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing);
- hepatitis, yellow coloration of the skin or the whites of the eyes (jaundice), hepatic failure (isolated cases of death or liver transplantation have been reported in patients with hepatic risk factors);
- hallucinations;
- inability to remain still (due to physical and mental unrest);
- inability to completely empty the bladder.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking Agomelatine Lupin

Storage

Keep Agomelatine Lupin 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.

Keep your tablets in a cool dry place where the temperature stays below 25°C in their original packaging in order to protect from moisture.

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

Do not leave Agomelatine Lupin in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Agomelatine Lupin is a yellow, oblong, biconvex, film-coated tablet.

Each pack contains 28 film-coated tablets.

Ingredients

Active ingredient

The active ingredient in Agomelatine Lupin is agomelatine. Each Agomelatine Lupin tablet contains 25 mg of agomelatine.

Inactive ingredients

The tablets also contain:

- silicified microcrystalline cellulose;
- mannitol;
- povidone;
- colloidal anhydrous silica;
- crospovidone;
- sodium stearyl fumarate;
- magnesium stearate.

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Australian Registration Numbers

Agomelatine Lupin 25 mg: AUST R 318688

Distributor

Generic Health Pty Ltd
Suite 2, Level 2
19-23 Prospect Street
Box Hill, VIC, 3128
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Agomelatine Lupin Patient Guide

IMPORTANT INFORMATION – DO NOT DISCARD!

Agomelatine Lupin is an antidepressant that can help you to treat depression.

To get the best from your medicine, follow your doctor's advice how to take Agomelatine Lupin, including dose, duration of treatment, associated follow up appointments, and blood tests.

Reporting of Side Effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to Generic Health using the contact details

at the end of this Patient Guide. This includes any possible side effects not listed in the Consumer Medicine Information. You can also report side effects directly via the national reporting scheme website:

<https://www.tga.gov.au/reporting-adverse-events>

By reporting side effects, you can help provide more information on the safety of this medicine.

Recommendations to Avoid Liver Side Effects

Agomelatine Lupin can cause side effects which may include changes in how your liver works.

This Patient Guide provides you with advice on:

- how to avoid liver side effects; and
- what to do if liver side effects occur during treatment with Agomelatine Lupin.

Ask your doctor if you have any queries regarding this or for any further information.

Ask your doctor for advice if you:

- have ever had liver problems;
- are obese or overweight;
- are diabetic;
- drink alcohol;
- are taking other medicines (some are known to affect the liver).

What to do to Avoid Liver Problems During Your Treatment

Have Regular Blood Tests

Why?

Your doctor will check that your liver is working properly **before starting the treatment** by running blood tests. The results will tell them **how your liver is working** and whether Agomelatine Lupin is suitable for you.

During treatment with Agomelatine Lupin, some patients may experience elevated levels of liver enzymes in their blood. The levels of these liver enzymes indicate whether your liver is working properly and are vital for the doctor when monitoring your treatment.

When?

Your doctor will perform blood tests:

- before starting treatment or at dose increases;
- after around 3 weeks;
- after around 6 weeks;
- after around 3 months; and
- after around 6 months.

If your doctor increases the dose to 50 mg, the tests must be performed again.

Tell your prescribing doctor immediately if you find out via another healthcare professional that your blood liver enzymes increase during treatment.

Be Vigilant About Signs of Liver Problems

If you observe any of the following, your liver may not be working properly:

- yellow skin/eyes;
- darkening of the urine;
- light coloured stools;
- pain in the upper right abdomen (belly);
- unusual fatigue (especially associated with other symptoms listed above).

Seek urgent advice from a doctor who may advise you to stop taking Agomelatine Lupin.

Your Blood Test Appointments

Remember: When taking Agomelatine Lupin, it is important that you have regular blood tests. The table below helps you to track your blood test appointments. **Remember to bring this with you when you visit your doctor.**

After Initiation of Treatment

Activity	Date
Agomelatine Lupin 25 mg – treatment start date	
Blood Tests for Liver Enzymes	
1 st test (at initiation of treatment)	
2 nd test (after around 3 weeks of treatment)	
3 rd test (after around 6 weeks of treatment)	
4 th test (after around 3 months of treatment)	
5 th test (after around 6 months of treatment)	

Your doctor will decide if any further tests should be taken. **Remember to bring this with you when you visit your doctor.**

After Dose Increase

Activity	Date
Agomelatine Lupin – dose increase to 50 mg	
Blood Tests for Liver Enzymes	
1 st test (at initiation of treatment)	
2 nd test (after around 3 weeks of treatment)	
3 rd test (after around 6 weeks of treatment)	
4 th test (after around 3 months of treatment)	
5 th test (after around 6 months of treatment)	

Your doctor will decide if any further tests should be taken. **Remember to bring this with you when you visit your doctor.**

Further Information

For further information, please contact your doctor or the Generic Health Medical Information Team on:

Phone: 03 9809 7900

Email: ghinfo@generichealth.com.au

