Agomelatine Lupin

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.

1. Why am I using Agomelatine Lupin?

Agomelatine Lupin contains the active ingredient agomelatine (as agomelatine-citric acid). Agomelatine Lupin is used in the treatment of depression and the prevention of relapse of depression. For more information, see Section 1. Why am I using Agomelatine Lupin? in the full CMI.

2. What should I know before I use Agomelatine Lupin?

Do not use if you have ever had an allergic reaction to agomelatine (as agomelatine-citric acid) or any of the ingredients listed at the end of the CMI. Do not use Agomelatine Lupin if you suffer from liver disease or you know your liver does not work properly (hepatic impairment).

Talk to your doctor or pharmacist 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 Agomelatine Lupin? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Agomelatine Lupin 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 Agomelatine Lupin?

- The usual dose of Agomelatine Lupin is one tablet at bedtime.
- In some cases your doctor may prescribe two tablets (50 mg) to be taken together at bedtime. You should not take more than the maximum recommended dose of two tablets daily.
- Do not change your dose without the advice of your doctor even if you feel better. Agomelatine Lupin can be taken with or without food.

More instructions can be found in Section 4. How do I use Agomelatine Lupin? in the full CMI.

5. What should I know while using Agomelatine Lupin?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Agomelatine Lupin. • Have blood tests to check your liver function 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, 6, 12 and 24 weeks.
Things you should not do	• You should not take Agomelatine Lupin together with certain medications, such as fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).
Driving or using machines	• As with all medications used to treat depression, you should make sure that you know how you react to Agomelatine Lupin before you drive or operate machinery.
Drinking alcohol	• It is recommended to avoid drinking alcohol while taking any antidepressant including Agomelatine Lupin. • People who drink excessive quantities of alcohol should not take Agomelatine Lupin. Excessive alcohol may cause liver problems and may make depression worse.
Looking after your medicine	• Keep your tablets in a cool, dry place where it stays below 25°C in their original packaging in order to protect from moisture.

For more information, see Section 5. What should I know while using Agomelatine Lupin? in the full CMI.

6. Are there any side effects?

As with all medications Agomelatine Lupin may cause unwanted side effects in some people. If you do experience any side effects, most of them are minor and temporary. Serious side effects, such as severe liver reactions (especially with excessive alcohol consumption and/or with any other medication processed by your liver) and severe allergic reactions, have very 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.

Agomelatine Lupin

Active ingredient(s): *agomelatine (as agomelatine-citric acid)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Agomelatine Lupin. **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 Agomelatine Lupin.**

Where to find information in this leaflet:

1. Why am I using Agomelatine Lupin?
2. What should I know before I use Agomelatine Lupin?
3. What if I am taking other medicines?
4. How do I use Agomelatine Lupin?
5. What should I know while using Agomelatine Lupin?
6. Are there any side effects?
7. Product details

1. Why am I using Agomelatine Lupin?

Agomelatine Lupin contains the active ingredient agomelatine.

Agomelatine Lupin is used in the treatment of depression and the prevention of relapse of depression.

The symptoms of depression vary from one person to another, but a depressive episode commonly includes 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.

Ask your doctor if you have any questions about why Agomelatine Lupin has been prescribed for you.

2. What should I know before I use Agomelatine Lupin?

Warnings

Do not use Agomelatine Lupin if:

- you are allergic to agomelatine, 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 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 medicine used in the treatment of depression) or ciprofloxacin (an antibiotic used to treat infections).
- the expiry date (EXP) printed on the pack has passed or the packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist if you:

- have ever experienced or develop an episode of bipolar disorder, mania or hypomania (extreme upward mood swings or irritable mood).
- have a history of dementia.
- are pregnant, plan to become pregnant or are breastfeeding.
- drink alcohol. 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.
- are smoking more than 15 cigarettes/day.
- have any doubts or questions about taking Agomelatine Lupin.

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).

Agomelatine Lupin is not addictive.

Agomelatine Lupin does not cause discontinuation symptoms on stopping treatment and can be stopped without the need to taper dose.

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 or pharmacist if you are pregnant or intend to become pregnant.

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

In clinical studies, Agomelatine Lupin had no effect on sexual function.

Use in the elderly

Agomelatine Lupin is not recommended elderly patients aged 75 or older.

Use in children

Agomelatine Lupin is not recommended for children or adolescents (under 18 years old).

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 Agomelatine Lupin and affect how it works. Medicines that may increase the effect of Agomelatine Lupin include:

- fluvoxamine (a medicine used in the treatment of depression);
- ciprofloxacin (an antibiotic used to treat infections);
- propranolol (a medicine sometimes used to treat heart problems).

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

4. How do I use Agomelatine Lupin?

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 two tablets, ie. 50 mg daily.
- Do not change your dose without the advice of your doctor even if you feel better.

When to take Agomelatine Lupin

- Agomelatine Lupin should be taken in the evening at bedtime.

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 Agomelatine Lupin should be used.
- Swallow Agomelatine Lupin tablets whole with some water in the evening at bedtime.
- Agomelatine Lupin can be taken with or without food.
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How long to take Agomelatine Lupin

- Current experience with agomelatine to treat depression shows that treatment for at least six months or longer provides the best opportunity of long-term recovery.
- Some people may experience improvements within two to four weeks if 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.
- When you and your doctor have decided to stop Agomelatine Lupin, there is no need to taper the dose as Agomelatine Lupin does not cause discontinuation symptoms after stopping treatment.

If you forget to use Agomelatine Lupin

Agomelatine Lupin should be used regularly at the same time each day.

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

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

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 as indicated on the tablet strip calendar.

The calendar printed on the tablet strip should help you remember when you last took a Agomelatine Lupin tablet. It is also a good reminder of how much Agomelatine Lupin you have left so you can get your prescription refilled if you need to.

If you use too much Agomelatine Lupin

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

If you think that you have used too much Agomelatine Lupin, you may need urgent medical attention.

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

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.

5. What should I know while using Agomelatine Lupin?

Your liver function

Agomelatine 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 should do

- To make sure you have the best opportunity of long-term recovery , continue to take Agomelatine Lupin as long as your doctor recommends you to.
- Tell your doctor if you have previously experienced a bipolar disorder or develop an episode of 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.
- 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.

Call your doctor straight away if:

- **you have any thoughts about suicide or doing harm to yourself. 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.
- **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 symptoms of 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 behavior, irritability or agitation.

  In addition to talking to your doctor, confidential support and counselling services are available. In Australia, call LifeLine on 13 11 14.
  You may find it helpful to tell a relative or close friend that you are depressed or anxious and ask them to read this leaflet. You might ask them to tell you if they think your symptoms are getting worse, or if they are worried about changes in your behaviour.

Remind any doctor, dentist or pharmacist you visit that you are using Agomelatine Lupin.

Things you should not do

- Do not stop using this medicine suddenly.
- **You should not take Agomelatine Lupin together with certain medications (see also under 'When you must not take Agomelatine Lupin'), including 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.

Driving or using machines

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

As with all medications used to treat depression, you should make sure that you know how you react to Agomelatine Lupin before you drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

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

Looking after your medicine

- Store below 25°C.
- Keep in the original packaging in order to protect from moisture.

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.

Keep it where young children cannot reach it.

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 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.

Agomelatine is usually well tolerated, increases in liver enzymes, and rarely inflammation of the liver, have been observed in some patients treated with agomelatine. When agomelatine 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.

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

Less serious side effects

Less serious side effects	What to do
Psychiatric disorders : • Agitation, irritability, restlessness, aggressive behaviour. • Mania/hypomania (see also under 'Before you start to take Agomelatine Lupin'). • Suicidal thoughts or behaviour • Nightmares. • Confusion. • Hallucinations. • Anxiety. **Nervous system disorders :** • Headache. • Migraine. • Dizziness, abnormal dreams.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**
• Sleepiness (somnolence). • difficulty in sleeping (insomnia). • 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). • Inability to remain still (due to physical and mental unrest). **Eye disorders:** • Blurred vision. **Ear disorders :** • Ringing in the ears. **Gastrointestinal Disorders:** • feeling sick (nausea), diarrhoea, constipation, abdominal pain, vomiting **Liver disorders :** • Increased levels of liver enzymes in your blood. • Hepatitis, yellow colouration 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). **Skin and subcutaneous tissue disorders:** • Eczema, pruritus, urticaria (hives). • Excessive sweating (hyperhidrosis). • 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). **Musculoskeletal and connective tissue disorders:** • Back pain, muscle pain. **Kidney and urinary disorders:** • Inability to completely empty the bladder. **General disorders:** • Weight increase. • Weight decrease.	

Less serious side effects	What to do
• Tiredness.	

Serious side effects

Serious side effects	What to do
Liver reactions: • **Severe liver reactions, 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. **Severe 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.	**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 Agomelatine Lupin contains

Active ingredient (main ingredient)	Agomelatine
Other ingredients (inactive ingredients)	Silicified microcrystalline cellulose Mannitol Povidone Colloidal anhydrous silica Crospovidone Sodium stearylfumarate Magnesium stearate
Potential allergens	Not applicable

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

Agomelatine Lupin tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes**.**

What Agomelatine Lupin looks like

Agomelatine Lupin is a yellow, oblong, biconvex, film-coated tablet (AUST R 318688).

Who distributes Agomelatine Lupin

Generic Health Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, VIC, 3128

Australia

✉ ghinfo@generichealth.com.au

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💻 www.generichealth.com.au

This leaflet was prepared in March 2025.

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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	
1st test (at initiation of treatment)	
2nd test (after around 3 weeks of treatment)	
3rd test (after around 6 weeks of treatment)	
4th test (after around 3 months of treatment)	
5th 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	
1st test (at initiation of treatment)	
2nd test (after around 3 weeks of treatment)	
3rd test (after around 6 weeks of treatment)	
4th test (after around 3 months of treatment)	
5th 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**