Package leaflet: Information for the patient

Lamegom 25 mg, filmomhulde tabletten
agomelatine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lamegom is and what it is used for

Lamegom contains the active ingredient agomelatine. It belongs to a group of medicines called antidepressants and you have been given Lamegom to treat your depression.

Lamegom is used in adults.

Depression is a continuing disturbance of mood that interferes with everyday life. The symptoms of depression vary from one person to another, but often include deep sadness, feelings of worthlessness, loss of interest in favourite activities, sleep disturbances, feeling of being slowed down, feelings of anxiety, changes in weight.
The expected benefits of Lamegom are to reduce and gradually remove the symptoms related to your depression.

2. What you need to know before you take Lamegom

Do not take Lamegom:
- if you are allergic to agomelatine or any of the other ingredients of this medicine (listed in section 6).
- **if your liver does not work properly (hepatic impairment).**
- if you are taking fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).

Warnings and precautions
There could be some reasons why Lamegom may not be suitable for you:
- If you are taking medicines known to affect the liver. Ask your doctor for advice on which medicine that is.
- If you are obese or overweight, ask your doctor for advice.
- If you are diabetic, ask your doctor for advice.

- If you have increased levels of liver enzymes before treatment, your doctor will decide if Lamegom is right for you.
- If you have bipolar disorder, have experienced or if you develop manic symptoms (a period of abnormally high excitability and emotions) talk to your doctor before you start taking this medicine or before you continue with this medicine (see also under "*Possible side effects*" in section 4).
- If you are suffering from dementia, your doctor will make an individual evaluation of whether it is right for you to take Lamegom.

During your treatment with Lamegom:

What to do to avoid potential serious liver problems
- Your doctor should have checked that your liver is working properly **before starting the treatment**. Some patients may get increased levels of liver enzymes in their blood during treatment with Lamegom. Therefore, follow-up tests should take place at the following time points:

	before initiation or dose increase	around 3 weeks	around 6 weeks	around 12 weeks	around 24 weeks
Blood tests	✓	✓	✓	✓	✓

Based on the evaluation of these tests your doctor will decide whether you should receive or continue using Lamegom (see also under "*How to take Lamegom*" in section 3).

Be vigilant about signs and symptoms that your liver may not be working properly
- **If you observe** any of these signs and symptoms of liver problems: **unusual darkening of the urine, light coloured stools, yellow skin/eyes, pain in the upper right belly, unusual fatigue (especially associated with other symptoms listed above), seek urgent advice from a doctor who may advise you to stop taking Lamegom.**

Effect of Lamegom is not documented in patients aged 75 years and older. Lamegom should therefore not be used in these patients.

Thoughts of suicide and worsening of your depression
If you are depressed, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:
- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (aged less than 25 years) with psychiatric conditions who were being treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

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.

Children and adolescents
Lamegom should not be used in children and adolescents (under 18 years old).

Other medicines and Lamegom
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should not take Lamegom together with certain medicines (see also under "*Do not take Lamegom*" in section 2): fluvoxamine (another medicine used in the treatment of depression), ciprofloxacin (an antibiotic) can modify the expected dose of agomelatine in your blood.
Make sure to tell your doctor if you are taking any of the following medicines: propranolol (a beta-blocker used in the treatment of hypertension), enoxacin (antibiotic).
Make sure to tell your doctor if you are smoking more than 15 cigarettes/day.

Lamegom with food, drink and alcohol
It is not advisable to drink alcohol while you are being treated with Lamegom.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breastfeeding should be discontinued if you take Lamegom.

Driving and using machines
You might experience dizziness or sleepiness which could affect your ability to drive or operate machines. Make sure that your reactions are normal before driving or operating machines.

Lamegom contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lamegom

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Lamegom is one tablet (25 mg) at bedtime. In some cases, your doctor may prescribe a higher dose (50 mg), i.e. two tablets to be taken together at bedtime.

Method of administration
Lamegom is for oral use. You should swallow your tablet with a drink of water. Lamegom can be taken with or without food.

Duration of treatment
Lamegom starts to act on symptoms of depression in most depressed people within two weeks of starting treatment. Your depression should be treated for a sufficient period of at least 6 months to ensure that you are free of symptoms.
Your doctor may continue to give you Lamegom when you are feeling better to prevent your depression from returning.
If you have trouble with your kidneys, your doctor will make an individual evaluation of whether it is safe for you to take Lamegom.

Surveillance of the liver function (see also section 2):
Your doctor will run laboratory tests to check that your liver is working properly before starting treatment and then periodically during treatment, usually after 3 weeks, 6 weeks, 12 weeks and 24 weeks.

If your doctor increase the dose to 50mg, laboratory tests should be performed at this initiation and then periodically during treatment, usually after 3 weeks, 6 weeks, 12 weeks and 24 weeks. Thereafter tests will be taken if the doctor finds it necessary.
You must not use Lamegom if your liver does not work properly.

How to switch from an antidepressant medicine (SSRI/SNRI) to Lamegom?
If your doctor changes your previous antidepressant medicine from an SSRI or SNRI to Lamegom, he/she will advise you on how you should discontinue your previous medicine when starting Lamegom.
You may experience discontinuation symptoms related to stopping of your previous medicine for a few weeks, even if the dose of your previous antidepressant medicine is decreased gradually.
Discontinuation symptoms include: dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking. These effects are usually mild to moderate and disappear spontaneously within a few days.
If Lamegom is initiated while tapering the dosage of the previous medicine, possible discontinuation symptoms should not be confounded with a lack of early effect of Lamegom.
You should discuss with your doctor on the best way of stopping your previous antidepressant medicine when starting Lamegom.

If you take more Lamegom than you should
If you have taken more Lamegom than you should, or if for example a child has taken medicine by accident, contact your doctor immediately.
The experience of overdoses with Lamegom is limited but reported symptoms include pain in the upper part of the stomach, somnolence, fatigue, agitation, anxiety, tension, dizziness, cyanosis or malaise.

If you forget to take Lamegom
Do not take a double dose to make up for a forgotten dose. Just carry on with the next dose at the usual time.

If you stop taking Lamegom
Do not stop taking your medicine without the advice of your doctor even if you feel better.

If you have any further questions on the use of this product, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most side effects are mild or moderate. They usually occur within the first two weeks of the treatment and are usually temporary.

These side effects include:
- Very common side effects (may affect more than 1 in 10 people): headache
- Common side effects (may affect up to 1 in 10 people): dizziness, sleepiness (somnolence), difficulty in sleeping (insomnia), feeling sick (nausea), diarrhoea, constipation, abdominal pain, back pain, tiredness, anxiety, abnormal dreams, increased levels of liver enzymes in your blood, vomiting, weight increased.
- Uncommon side effects (may affect up to 1 in 100 people): migraine, pins and needles in the fingers and toes (paraesthesia), blurred vision, restless legs syndrome (a disorder that is

characterized by an uncontrollable urge to move the legs), ringing in the ears, excessive sweating (hyperhidrosis), eczema, pruritus, urticaria (hives), agitation, irritability, restlessness, aggressive behaviour, nightmares, mania/hypomania (see also under “Warnings and precautions” in section 2), suicidal thoughts or behaviour, confusion, weight decreased, muscle pain.
- 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*, hallucinations, inability to remain still (due to physical and mental unrest), inability to completely empty the bladder. * Few cases resulting in liver transplantation or death have been reported.

Het melden van bijwerkingen
Krijgt u last van bijwerkingen, neem dan contact op met uw arts of apotheker. Dit geldt ook voor mogelijke bijwerkingen die niet in deze bijsluiter staan. U kunt bijwerkingen ook rechtstreeks melden via Nederlands Bijwerkingen Centrum Lareb. Website: www.lareb.nl. Door bijwerkingen te melden kunt u ons helpen meer informatie te verkrijgen over de veiligheid van dit geneesmiddel.

5. How to store Lamegom

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.
This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lamegom contains
- The active substance is agomelatine. Each film-coated tablet contains agomelatine-citric acid equivalent to 25 mg agomelatine.
- The other ingredients are colloidal silicified dioxide, microcrystalline cellulose, mannitol, povidone 30, colloidal anhydrous silica, crospovidone, sodium stearyl fumarate, magnesium stearate, stearic acid in the tablet core and hypromellose, macrogol, titanium dioxide (E171), talc, yellow iron oxide (E172) in the film coating.
  See section 2 "Lamegom contains sodium".

What Lamegom looks like and contents of the pack
Lamegom 25 mg film-coated tablets (tablets) are yellow, oblong, biconvex film-coated tablets 9 x 4.5 mm.

Lamegom 25 mg film-coated tablets are available in blisters. Packs contain 28, 30, 56, 84 or 98 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

1.3.1	Agomelatine
SPC, Labeling and Package Leaflet	NL-Netherlands

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenië

Manufacturer
MEDIS International a.s., vyrobni zavod Bolatice
Prumyslova 961/16
747 23 Bolatice
Tsjechië

In het register ingeschreven onder: RVG 122591

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Naam van de lidstaat	**Naam van het medicijn**
Nederland, Tsjechië, Slowakijke, Litouwen, Letland, Estland, Polen, Hongarije	Lamegom

Deze bijsluiter is voor het laatst goedgekeurd in april 2021.