Bijsluiter: informatie voor de patiënt

Agomelatine betapharm 25 mg filmomhulde tabletten

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 Agomelatine betapharm is and what it is used for

Agomelatine betapharm contains the active ingredient agomelatine. It belongs to a group of medicines called antidepressants. You have been given Agomelatine betapharm to treat your depression.

Agomelatine betapharm 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 Agomelatine betapharm are to reduce and gradually remove the symptoms related to your depression.

2. What you need to know before you take Agomelatine betapharm

Do not take Agomelatine betapharm
- 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 Agomelatine betapharm 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 Agomelatine betapharm 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 Agomelatine betapharm.

During your treatment with Agomelatine betapharm:
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 agomelatine. 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 Agomelatine betapharm (see also under "*How to take Agomelatine betapharm*" 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 Agomelatine betapharm.**

Effect of agomelatine is not documented in patients aged 75 years and older. Agomelatine betapharm 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
Agomelatine betapharm is not recommended in children below 7 years due to lack of information. No data is available.

Agomelatine betapharm should not be used in children and adolescents aged 7 to 17 years because safety and efficacy have not been established.

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

You should not take Agomelatine betapharm together with certain medicines (see also under " *Do not take Agomelatine betapharm*" 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.

Agomelatine betapharm with alcohol
It is not advisable to drink alcohol while you are being treated with Agomelatine betapharm.

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.

Breast-feeding should be discontinued if you take Agomelatine betapharm.

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.

Agomelatine betapharm 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 Agomelatine betapharm

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

Duration of treatment
Agomelatine 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 Agomelatine betapharm 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 Agomelatine betapharm.

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 increases the dose to 50 mg, 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 Agomelatine betapharm if your liver does not work properly.

How to switch from an antidepressant medicine (SSRI/SNRI) to Agomelatine betapharm?
If your doctor changes your previous antidepressant medicine from an SSRI or SNRI to Agomelatine betapharm, he/she will advise you on how you should discontinue your previous medicine when starting Agomelatine betapharm.
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 Agomelatine betapharm is initiated while tapering the dosage of the previous medicine, possible discontinuation symptoms should not be confounded with a lack of early effect of Agomelatine betapharm.
You should discuss with your doctor on the best way of stopping your previous antidepressant medicine when starting Agomelatine betapharm.

If you take more Agomelatine betapharm than you should
If you have taken more Agomelatine betapharm than you should, or if for example a child has taken medicine by accident, contact your doctor immediately.
The experience of overdoses with agomelatine 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 Agomelatine betapharm
Do not take a double dose to make up for a forgotten dose. Just carry on with the next dose at the usual time.

The calendar printed on the blister containing the tablets should help you remembering when you last took a tablet of Agomelatine betapharm.

If you stop taking Agomelatine betapharm
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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Agomelatine betapharm

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 carton and blister. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. This medicinal product 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 to protect the environment.

6. Contents of the pack and other information

What Agomelatine betapharm contains
- The active substance is agomelatine. Each film-coated tablet contains agomelatine-citric acid co-crystal equivalent to 25 mg of agomelatine.
- The other ingredients are:
  - Tablet core: silicified microcrystalline cellulose, mannitol, povidone 30, colloidal anhydrous silica, crospovidone, sodium stearyl fumarate, magnesium stearate and stearic acid.
  - Film-coating: hypromellose, macrogol, titanium dioxide (E171), talc and yellow iron oxide (E172).

What Agomelatine betapharm looks like and contents of the pack
Agomelatine betapharm 25 mg film-coated tablets are yellow, oblong, biconvex, 9 mm long and 4.5 mm wide film-coated tablets.

Agomelatine betapharm 25 mg film-coated tablets are available in blisters containing 7, 14, 28, 42, 56, 84, 98 or 100 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen

betapharm Arzneimittel GmbH
Kobelweg 95
86156 Augsburg
Duitsland

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

In het register ingeschreven onder: RVG 122588

This medicinal product is authorised in the Member States of the EEA under the following names:

Duitsland:	Agomelatin beta 25 mg Filmtabletten
Nederland:	Agomelatine betapharm 25 mg filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in september 2025.