

## **Package leaflet: Information for the patient**

### **Agomelatine Rowex 25 mg Film-coated tablets**

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 Agomelatine Rowex is and what it is used for
2. What you need to know before you take Agomelatine Rowex
3. How to take Agomelatine Rowex
4. Possible side effects
5. How to store Agomelatine Rowex
6. Contents of the pack and other information

#### **1. What Agomelatine Rowex is and what it is used for**

Agomelatine Rowex contains the active substance agomelatine. It belongs to a group of medicines called antidepressants and you have been given Agomelatine Rowex to treat your depression. Agomelatine Rowex 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 Rowex are to reduce and gradually remove the symptoms related to your depression.

#### **2. What you need to know before you take Agomelatine Rowex**

##### **Do not take Agomelatine Rowex**

- 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**

Talk to your doctor or pharmacist before taking Agomelatine Rowex.

There could be some reasons why Agomelatine Rowex 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 Rowex 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 Rowex.

During your treatment with Agomelatine Rowex:

#### 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 Rowex. 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 Rowex (see also under “**How to take Agomelatine Rowex**” 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 Rowex.**

#### 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.

#### Elderly

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

#### Children and adolescents

Agomelatine Rowex is not intended for use in children and adolescents (under 18 years old).

#### Other medicines and Agomelatine Rowex

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

You should NOT take Agomelatine Rowex together with certain medicines (see also under “**Do not take Agomelatine Rowex**” in section 2):

fluvoxamine (another medicine used in the treatment of depression), ciprofloxacin (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), rifampicin (antibiotic) and if you are smoking more than 15 cigarettes/day.

### **Agomelatine Rowex with alcohol**

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

### **Pregnancy and breast-feeding**

#### **Pregnancy**

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**

Talk to your doctor if you are breast-feeding or intending to breast-feed as breast-feeding should be discontinued if you take Agomelatine Rowex.

### **Driving and using machines**

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

### **Agomelatine Rowex contains lactose and sodium**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

## **3. How to take Agomelatine Rowex**

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 Rowex 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.

Agomelatine Rowex starts to act on symptoms of depression in most depressed people within two weeks of starting treatment. Your doctor may continue to give you Agomelatine Rowex when you are feeling better to prevent your depression from returning.

### **How to switch from an antidepressant medicine (SSRI/SNRI) to Agomelatine Rowex?**

If your doctor changes your previous antidepressant medicine from an SSRI or SNRI to Agomelatine Rowex, he/she will advise you on how you should discontinue your previous medicine when starting Agomelatine Rowex.

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 Rowex is initiated while tapering the dose of the previous medicine, possible discontinuation symptoms should not be confounded with a lack of early effect of Agomelatine Rowex.

You should discuss with your doctor on the best way of stopping your previous antidepressant medicine when starting Agomelatine Rowex.

**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** take Agomelatine Rowex if your liver does not work properly.

If you have trouble with your kidneys, your doctor will make an individual evaluation of whether it is safe for you to take Agomelatine Rowex.

**Method of administration**

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

**Duration of treatment**

Your depression should be treated for a sufficient period of at least 6 months to ensure that you are free of symptoms.

**If you take more Agomelatine Rowex than you should**

If you have taken more Agomelatine Rowex 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 Rowex**

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, if printed on the blister containing the tablets, should help you remembering when you last took a tablet of Agomelatine Rowex.

**If you stop taking Agomelatine Rowex**

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 medicine, 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)
- angioedema (swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing)
- hepatitis
- yellow colouration of the skin or the whites of the eyes (jaundice)
- hepatic failure (few cases resulting in liver transplantation or death have been reported)
- hallucinations
- inability to remain still (due to physical and mental unrest)

- inability to completely empty the bladder.

### **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: HPRRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Agomelatine Rowex**

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 after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special 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 Rowex contains**

- The active substance is agomelatine.  
Each film-coated tablet contains 25 mg of agomelatine (as agomelatine urea).
- The other ingredients are:
  - **tablet core:** lactose monohydrate, calcium hydrogen phosphate dihydrate, sodium starch glycolate (type A), colloidal anhydrous silica, magnesium stearate.
  - **tablet coating:** lactose monohydrate, hypromellose, yellow iron oxide (E172), macrogol 4000, titanium dioxide (E171).

### **What Agomelatine Rowex looks like and contents of the pack**

Agomelatine Rowex 25 mg film-coated tablets are dark yellow, oval, biconvex film-coated tablets, debossed with 25 on one side. Dimensions: approximately 8.5 mm x 4.5 mm.

The film-coated tablets are packed in OPA/Al/PE + calcium oxide desiccant//Al/PE blisters (calendar) and inserted in a carton.

Pack sizes:

7, 14, 28, 42, 56, 84, 98 and 100 film-coated tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

#### **Manufacturers**

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

PLIVA Croatia Ltd., Prilaz baruna Filipovića 25, Zagreb 10000, Croatia.

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

Germany:	Agomelatin HEXAL® 25 mg Filmtabletten
Denmark:	Agomelatin Sandoz
Finland:	Agomelatin Sandoz 25 mg kalvopäällysteiset tabletit
Ireland:	Agomelatine Rowex 25mg Film-coated tablets

Netherlands: Agomelatine Sandoz 25 mg, filmomhulde tabletten  
Slovakia: Agomelatine Sandoz 25 mg  
Spain: Agomelatina Sandoz 25 mg comprimidos recubiertos con película EFG  
Sweden: Agomelatin Sandoz 25 mg filmdragerade tabletter

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