REPORTING SIDE EFFECTS

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in the information leaflet.
You can also report side effects to the Health Products Regulatory Authority via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Side effects can also be reported to Accord Healthcare Ireland Ltd.
via E-mail: medinfo@accord-healthcare.com; Tel: +44 (0) 1271 385 257;
or by completing the online form at www.accord-healthcare.ie/drug-reaction-report or to McDermott Laboratories Ltd t/a Gerard Laboratories, Email: ukpharmacovigilance@mylan.com Tel:+44 174 882 8888.

Date of Preparation: February 2019

PATIENT BOOKLET

IMPORTANT INFORMATION - DO NOT DISCARD!

Agomelatine 25 mg Film-Coated Tablets

RECOMMENDATIONS TO AVOID LIVER SIDE EFFECTS

This is risk minimisation material and is provided as a collaborative project between Accord Healthcare ireland Ltd and (Mylan) McDermott Laboratories Ltd t/a Gerard Laboratories. For further information, please refer to the Patient Information Lealfet (PIL) for the respective medicinal products from the relevant Marketing Authorisation Holder available at www.hpra.ie.

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

This booklet provides you with advice on how to avoid liver side effects and what to do if such side effects occur during Agomelatine treatment. Ask your doctor for any further information.

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

In order to optimize your medical care, follow the recommendations of your doctor regarding the intake of Agomelatine treatment including; dose, duration of treatment, associated follow up such as scheduled appointments and blood tests analysis.

WHAT TO DO BEFORE TAKING AGOMELATINE?

Tell your doctor if you know that you have liver problems: do not take Agomelatine if this is the case.
There could be other reasons why Agomelatine may not be suitable for you.
Please ask your doctor for advice on the following:

- If you ever had liver problems,
- If you are obese or overweight,
- If you are diabetic,
- If you consume alcohol,
- If you 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 should have checked that your liver is working properly before starting the treatment. The blood tests prescribed by your doctor will tell her/him how your liver is working and help your doctor decide if Agomelatine is suitable for you.
  During treatment with Agomelatine, some patients may get increased levels of liver enzymes in their blood. The levels of these liver enzymes indicate whether your liver is working properly and provide vital information for the doctor when monitoring your treatment.

- **When?**

	Start of Treatment or Increase of Dose	Around 3 weeks	Around 6 weeks	Around 3 months	Around 6 months
Blood Tests	✓	✓	✓	✓	✓

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

Don't forget to bring this booklet to your doctor as it contains your BLOOD TESTS APPOINTMENT REMINDER (see next page).

Tell your doctor immediately if you get any information that your blood liver enzymes have increased 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.**

YOUR BLOOD TESTS APPOINTMENTS REMINDER

REMEMBER
When taking Agomelatine, it is important that you have regular blood tests.
The table below helps you to track your blood tests appointments.

AGOMELATINE 25 MG FILM-COATED TABLETS	DATE
Treatment start date:	
Blood test intervals for liver enzymes	
Date of first test *(at initiation)*:	
Date of second test *(after around 3 weeks)*:	
Date of third test *(after around 6 weeks)*:	
Date of fourth test *(after around 3 months)*:	
Date of fifth test *(after around 6 months)*:	

Your doctor will decide if further blood tests should be taken

DOSE INCREASE TO 50 MG	DATE
Treatment start date:	
Blood test intervals for liver enzymes	
Date of first test *(at initiation of 50 mg)*:	
Date of second test *(after around 3 weeks)*:	
Date of third test *(after around 6 weeks)*:	
Date of fourth test *(after around 3 months)*:	
Date of fifth test *(after around 6 months)*:	

Your doctor will decide if further blood tests should be taken and will monitor your blood tests according to a Liver Monitoring Scheme.

Remember to bring this booklet with you when you visit your doctor.

For more detailed information, please refer to the patient information leaflet in the Agomelatine package.