

Important Information for Patients about Agomelatine

Recommendations to avoid liver side effects

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

Agomelatine can cause side effects which may include changes to your liver functioning

This guide provides you with recommendations on how to avoid liver side effects and advice on what to do if such side effects occur during agomelatine treatment.

Ask your doctor or pharmacist for any further information. Follow the recommendations of your doctor about agomelatine treatment (dose, duration of treatment, follow ups such as scheduled appointments, blood tests analysis).

WHAT TO DO BEFORE TAKING AGOMELATINE

Tell your doctor if you know that your liver does not work properly: do not take agomelatine in this 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 have 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 to 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 the proper or improper functioning of your liver and are vital for the doctor when monitoring your treatment.

When?

- before initiation or dose increase
- around 3 weeks
- around 6 weeks
- around 3 months
- around 6 months

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

Don't forget to bring your **BLOOD TESTS APPOINTMENTS REMINDER** to your doctor.

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

➤ **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 belly
- unusual fatigue (especially associated with the 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 START DATE:	
Blood test intervals for liver enzymes	DATE
Date of first test (<i>at initiation</i>)	
Date of second test (<i>after around 3 weeks</i>)	
Date of third test (<i>after around 6 weeks</i>)	

Date of fourth test (<i>after around 3 months</i>)	
Date of fifth test (<i>after around 6 months</i>)	

Your doctor can decide that further blood tests should be taken.

DOSE INCREASE TO 50 MG START DATE:	
Blood test intervals for liver enzymes	DATE
Date of test at initiation of agomelatine 50 mg	
Date of second test (<i>after around 3 weeks</i>)	
Date of third test (<i>after around 6 weeks</i>)	
Date of fourth test (<i>after around 3 months</i>)	
Date of fifth test (<i>after around 6 months</i>)	

Your doctor can decide that further blood tests should be taken.

Do not forget to bring this guide with you when you visit your doctor.