

⇒ **Seek urgent advice from a doctor who may advise you to stop taking Agomelatine.**

- 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)

If you observe any of the following, your liver may not be working properly:

➤ **Be vigilant about signs of liver problems**

Tell your doctor immediately if you find out that your blood liver enzymes increase during treatment.

Remember to bring your blood tests appointment reminder with you to your doctor

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

When?

YOUR BLOOD TEST APPOINTMENTS

REMEMBER

When taking Agomelatine, it is important that you have regular blood tests.

The table below helps you to track your blood test appointments.

AGOMELATINE 25 mg - Treatment start

Test at start of Agomelatine 50 mg

Your doctor will decide if any further tests should be taken.

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

Provided By Mint Health LTD.

During treatment with Agomelatine, some patients may experience increased levels of liver enzymes in their blood. The levels of these liver enzymes indicate whether your liver is working properly and are vital for the doctor when monitoring your treatment.

Your doctor will check that your liver is working properly before starting the treatment by running blood tests. The results will tell her/him **how your liver is working** and whether Agomelatine is suitable for you.

Why?

➤ **Have regular blood tests**

What to do to avoid liver problems during your treatment

- 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 drink alcohol
 - if you are taking other medicines (some are known to affect the liver)

not be suitable for you.

➤ **problems: do not take Agomelatine if this is the case.**

➤ **Tell your doctor if you know that you have liver**

What to do before taking Agomelatine

Patient Alert Card

AGOMELATINE - ARISTO

Agomelatine is an antidepressant that can help you to treat depression. To get the best from your medicine, follow your doctor's advice on how to take Agomelatine (dose, duration of treatment, associated follow up appointments, blood tests).

Recommendations to avoid liver side effects

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

This guide provides you with recommendations on:

- **how to avoid liver side effects**
- **what to do if liver side effects occur during Agomelatine treatment**

Ask your doctor for any further information.

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

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 the patient information leaflet. You can report side effects to MINT Health Ltd, 3/4, Cantrija Complex, Triq it-Targa, Il-Maghtab, Naxxar NXR6613 Malta. Tel: +356 2755 9990, Email: pharmacovigilancemt@mint.com.mt or via the following Website: www.medicinesauthority.gov.mt/adrportal Alternatively Local ADR reporting address, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta Email: postlicensing.medicinesauthority@gov.mt



By reporting side effects you can help provide more information on the safety of this medicine.

Cut line

Fold line



Fold in half again



Cut out the alert card from the printed sheet and fold in half



Patient Alert Card INSTRUCTIONS

