

VALDOXAN

(agomelatine)

Recommendations to avoid liver side effects

Valdoxan can cause side effects which may include changes in your liver functioning.

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

Ask your doctor for any further information.

Valdoxan 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 Valdoxan treatment (dose, duration of treatment, associated follow up such as scheduled appointments, blood tests analysis).

WHAT TO DO BEFORE TAKING VALDOXAN?

- **Tell your doctor if you know that your liver does not work properly: do not take Valdoxan in this case.**
- There could be **other reasons why Valdoxan 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 to decide if Valdoxan is suitable for you.

During treatment with Valdoxan, 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
Blood Tests	✓	✓	✓	✓	✓

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

Don't forget to bring your **BLOOD TESTS APPOINTMENTS REMINDER**
(see next page) to your doctor.

Inform your doctor immediately if you get any information that your blood liver enzymes increase during treatment.

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

If you observe any of the followings, 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 other symptoms listed above)

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

YOUR BLOOD TESTS APPOINTMENTS REMINDER

REMEMBER

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

THE TABLE BELOW HELPS YOU TO TRACK YOUR BLOOD TESTS APPOINTMENTS.

VALDOXAN 25 MG – FIRST INTAKE 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 - FIRST INTAKE DATE:	
Blood test intervals for liver enzymes	Date
Date of test at initiation of Valdoxan 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.

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

Adverse events should be reported to the Medicines Authority Post-licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta or at:
www.medicinesauthority.gov.mt/adrportal