Patient Information

Booklet

Risk minimization measures have been approved by Saudi Food and Drug Authority (SFDA).

Valdoxan®

film-coated tablets Agomelatine

Version Date: 12. 2021
Version Number: 1

Recommendations to avoid the occurrence of side effects on the liver

Valdoxan use may cause side effects, which may include changes in liver function.

This booklet provides recommendations to avoid the occurrence of side effects on the liver, as well as what you should do in case you face such side effects during your treatment with Valdoxan.
Consult your doctor for any additional information you might need.

Valdoxan is an antidepressant which may help in treating your depression.

To get the best level of medical care, you should follow your doctor instructions carefully on how to use Valdoxan (dose, duration of treatment, and all what is related to the treatment such as doctor's appointments and blood tests).

What you should do before you take Valdoxan?

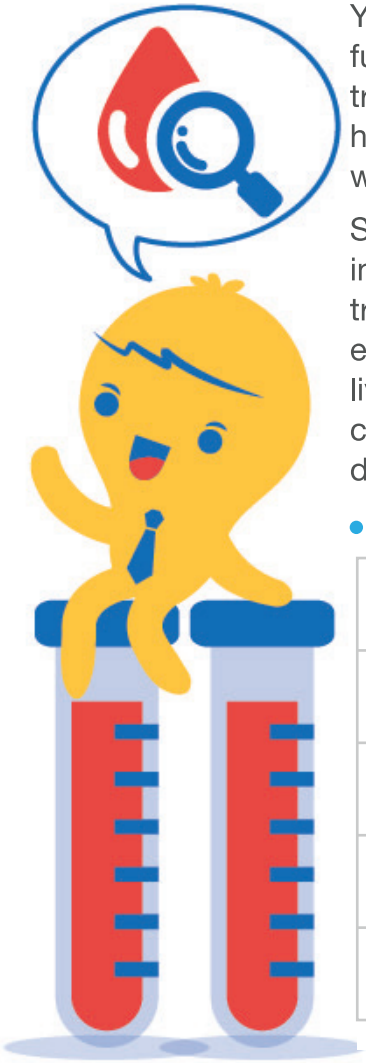
- Inform your doctor if you know that your liver does not function properly; you should not take Valdoxan in this case.
- There might be other reasons that make Valdoxan unsuitable for you.

Please consult your doctor regarding the following points:

- If you have ever had liver problems,
- If you are obese or overweight,
- If you have diabetes,
- If you consume alcohol,
- If you are taking other medicines (which are known to have an effect on the liver).

What you should do to avoid liver problems during the period of treatment?

√ Undertake regular blood tests



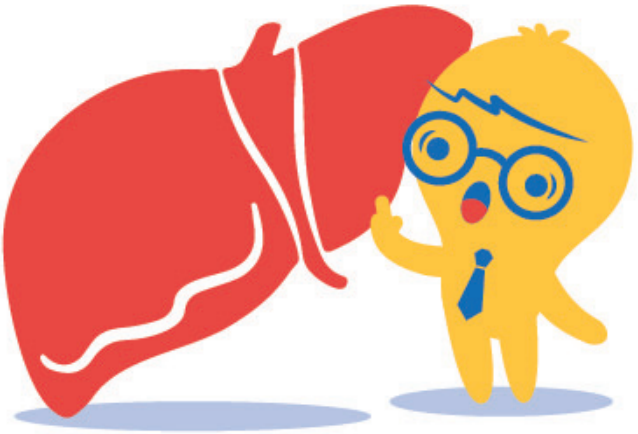
- **Why?**

Your doctor must check that your liver is functioning properly before starting the treatment. Such blood tests will show him/her how the liver is working, as well as whether Valdoxan is appropriate for you.

Some patients may experience an increase in liver enzymes in the blood during their treatment with Valdoxan. These blood enzyme levels indicate whether or not the liver is functioning properly, and they constitute an important indicator for the doctor in monitoring your treatment.

- **When?**

	Blood tests
At the beginning of the treatment or upon any dose increments	√
Around the third week	√
Around the sixth week	√
Around the third month	√
Around the sixth month	√



If your doctor increases the Valdoxan dose for you to 50 mg, you should redo the blood tests.
Do not forget to bring your blood test appointment calendar during your visit to the doctor (see next page).
Tell your doctor immediately if you know that you developed an increase in liver enzymes in your blood during treatment.

You should be on alert for symptoms of liver problems if you notice any of the following, which may indicate that your liver is not functioning properly:

- √ Yellowing of skin/eyes
- √ Dark yellow urine
- √ Light stool color
- √ Pain in the upper right abdomen
- √ Unusual tiredness (especially concurrently with the other symptoms listed above)

Seek immediate medical advice from your doctor, who may advise you to stop taking the medication.

Your blood test appointment calendar

Remember: it is important to undertake regular blood tests during your treatment with Valdoxan.

The following table helps you keep track of your blood test appointments

Valdoxan 25 mg – Treatment Start Date	
Time interval for liver enzyme level test	Date
1st blood test date (At the beginning of the treatment)	
2nd blood test date (3 weeks after the beginning of the treatment)	
3rd blood test date (6 weeks after the beginning of the treatment)	
4th blood test date (3 months after the beginning of the treatment)	
5th blood test date (6 months after the beginning of the treatment)	

Your doctor might decide to perform additional blood tests for you.

Valdoxan dose increase to 50 mg – Treatment start date	
Time interval for liver enzyme level test	Date
1st blood test date (At the beginning of the treatment)	
2nd blood test date (3 weeks after the beginning of the treatment)	
3rd blood test date (6 weeks after the beginning of the treatment)	
4th blood test date (3 months after the beginning of the treatment)	
5th blood test date (6 months after the beginning of the treatment)	

Your doctor might decide to perform additional blood tests for you.

Do not forget to bring this calendar with you during your visits to the doctor.

To get more detailed information, please refer to the patient information leaflet enclosed within the package.

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Any suspected adverse events should be reported to the national spontaneous reporting system according to the national regulations.
SFDA (National pharmacovigilance and drug safety Center)
Email to: npc.drug@sfda.sa
Fax: Fax: +966-11-2057662
Online: http://ade.sfda.gov.sa/
Toll free number: 8002490000

SFDA call center: 19999

Or you can contact company scientific office at:
Tel.: +966 011 252 2330 / +966 (0)5 55 07 08 17
E-mail: regulatory.sa1@servier.com / pv.sa1@servier.com

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12_2021_VALDOXAN_RMM_1.0