

PACKAGE LEAFLET: INFORMATION FOR THE USER

Valdoxan 25 mg film-coated tablets Agomelatine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Valdoxan is and what it is used for
2. Before you take Valdoxan
3. How to take Valdoxan
4. Possible side effects
5. How to store Valdoxan
6. Further information

1. WHAT VALDOXAN IS AND WHAT IT IS USED FOR

Valdoxan belongs to a group of medicines called antidepressants and you have been given Valdoxan to treat your depression.

Depression is a continuing disturbance of mood that interferes with everyday life. The symptoms of depression vary from one person to another, but often include deep sadness, feelings of worthlessness, loss of interest in favourite activities, sleep disturbances, feeling of being slowed down, feelings of anxiety, changes in weight.

2. BEFORE YOU TAKE VALDOXAN

Do not take Valdoxan

- if you are allergic (hypersensitive) to agomelatine or any of the other ingredients of Valdoxan (see '*What Valdoxan contains*' in section 6).
- if you are taking fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).
- if your liver does not work properly (hepatic impairment).

Take special care with Valdoxan

There could be some reasons why Valdoxan may not be suitable for you:

- If you have bipolar disorder, have experienced or if you develop manic symptoms (a period of abnormally high excitability and emotions) talk to your doctor before you start taking this medicine or before you continue with this medicine (see also under "*Possible side effects*" in section 4).
- If you are taking medicine known to affect the liver. Ask your doctor for advice on which medicine that is.
- If you are obese or overweight, ask for your doctor for advice.

- If you have increased levels of liver enzymes before treatment, your doctor will decide if Valdoxan is right for you.
- Some patients may get increased levels of liver enzymes in their blood during treatment with Valdoxan. Your doctor will therefore run laboratory tests to check that your liver is working properly at the initiation of the treatment and then periodically during treatment. Based on the evaluation of these tests the doctor will decide whether you should continue using Valdoxan or not (see also under “*How to take Valdoxan*” in section 3).
- If you are suffering from dementia, your doctor will make an individual evaluation of whether it is safe for you to take Valdoxan.

Valdoxan is not intended for use in children and adolescents (under 18 years old).

Thoughts of suicide and worsening of your depression

If you are depressed you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (aged less than 25 years) with psychiatric conditions who were being treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not take Valdoxan together with certain medicines (see also under “*Do not take Valdoxan*” in section 2): fluvoxamine (another medicine used in the treatment of depression), ciprofloxacin (an antibiotic).

Taking Valdoxan with food and drink

Valdoxan can be taken with or without food.

It is not advisable to drink alcohol while you are being treated with Valdoxan.

Pregnancy

Talk to your doctor if you become pregnant (or plan to become pregnant) while you are taking Valdoxan. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Talk to your doctor if you are breast-feeding or intending to breast-feed as breastfeeding should be discontinued if you take Valdoxan.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You might experience dizziness or sleepiness which could affect your ability to drive or operate machinery. Make sure that your reactions are normal before driving or operating machines.

Important information about some of the ingredients of Valdoxan

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking Valdoxan.

3. HOW TO TAKE VALDOXAN

Always take Valdoxan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose of Valdoxan is one tablet (25 mg) at bedtime. In some cases, your doctor may prescribe a higher dose (50 mg), i.e. two tablets to be taken together at bedtime.

Valdoxan starts to act on symptoms of depression in most depressed people within two weeks of starting treatment. Your doctor may continue to give you Valdoxan when you are feeling better to prevent your depression from returning.

Do not stop taking your medicine without the advice of your doctor even if you feel better.

Valdoxan is for oral use. You should swallow your tablet with a drink of water. Valdoxan can be taken with or without food.

Your doctor will run laboratory tests to check that your liver is working properly at the initiation of treatment and then periodically during treatment, usually after 6 weeks, 12 weeks and 24 weeks.

Thereafter tests will be taken if the doctor finds it necessary.

You must not use Valdoxan if your liver does not work properly.

If you have trouble with your kidneys, your doctor will make an individual evaluation of whether it is safe for you to take Valdoxan.

If you take more Valdoxan than you should

If you have taken more Valdoxan than you should, or if for example a child has taken medicine by accident, contact your doctor immediately.

The experience of overdoses with Valdoxan is limited but reported symptoms include pain in the upper part of the stomach , somnolence, fatigue, agitation, anxiety, tension, dizziness, cyanosis or malaise.

If you forget to take Valdoxan

Do not take a double dose to make up for a forgotten dose. Just carry on with the next dose at the usual time.

The calendar printed on the blister containing the tablets should help you remembering when you last took a tablet of Valdoxan.

If you have any further questions on the use of this product, please ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Valdoxan can cause side effects, although not everybody gets them.

Most side effects are mild or moderate. They usually occur within the first two weeks of the treatment and are usually temporary.

The frequency of possible side effects listed below is defined using the following system:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

These side effects include:

- Common side effects: dizziness, sleepiness (somnolence), difficulty in sleeping (insomnia), migraine, headache, feeling sick (nausea), diarrhoea, constipation, abdominal pain, excessive sweating (hyperhidrosis), back pain, tiredness, anxiety, increased levels of liver enzymes in your blood.
- Uncommon side effects: pins and needles in the fingers and toes (paraesthesia), blurred vision and eczema.
- Rare side effects: serious skin eruption (erythematous rash), hepatitis.
- Other possible side effects: Frequency not known : suicidal thoughts or behaviour, mania/hypomania (see also under “*Take special care with Valdoxan*” in section 2), agitation, irritability, restlessness, aggressive behaviour, nightmares, abnormal dreams and pruritus.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE VALDOXAN

Keep out of the reach and sight of children.

Do not use Valdoxan after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Valdoxan contains

- The active substance is agomelatine. Each tablet contains 25 mg of agomelatine.
- The other ingredients are:
 - tablet core: lactose monohydrate, maize starch, povidone, sodium starch glycolate type A, stearic acid, magnesium stearate, colloidal anhydrous silica.

- tablet film-coating: hypromellose, glycerol, macrogol, magnesium stearate, yellow iron oxide (E172) and titanium dioxide (E171).
- printing ink : shellac, propylene glycol and indigotine (E132) aluminium lake

What Valdoxan looks like and contents of the pack

Valdoxan 25 mg film-coated tablets are oblong, orange-yellow with a blue imprint of 'company logo'  on one side.

Valdoxan 25 mg film-coated tablets are available in calendar blisters. Packs contain 7, 14, 28, 42, 56, 84 or 98 tablets. Packs of 100 film-coated tablets are also available for hospital use. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved in {date}

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site
<http://www.ema.europa.eu>