

VALDOXAN 25MG FILM-COATED TABLETS

Agomelatine 25mg

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What Valdoxan is used for

Valdoxan is used in adult to treat depression or generalised anxiety disorder.

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.

Generalised anxiety disorder is a chronic feeling of anxiety or nervousness with sleep disorders, and physical symptoms such as fatigue and muscle tension.

How Valdoxan works

Valdoxan contains the active ingredient agomelatine. It belongs to a group of medicines called antidepressants.

The expected benefits of Valdoxan are to reduce and gradually remove the symptoms related to your depression or generalised anxiety disorder.

Before you take Valdoxan

- When you must not use it

Do not take Valdoxan

- if you are allergic to agomelatine or any of the other ingredients of this medicine (listed in section 8).

- **if your liver does not work properly (hepatic impairment).**

- if you are taking fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).

Pregnancy and breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breastfeeding should be discontinued if you take Valdoxan.

- Before you start to take it

Warnings and precautions

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

- 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 your doctor for advice.
- If you are diabetic, ask your doctor for advice
- If you have increased levels of liver enzymes before treatment, your doctor will decide if Valdoxan is right 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 "Side effects" in section 6).
- If you are suffering from dementia, your doctor will make an individual evaluation of whether it is safe for you to take Valdoxan.

During your treatment with Valdoxan:

What to do to avoid potential serious liver problems

- Your doctor should have checked that your liver is working properly **before starting the treatment.** Some patients may get increased levels of liver enzymes in their blood during treatment with Valdoxan. Therefore, follow-up tests should take place at the following time points:

	Blood tests
before initiation or dose increase	✓
around 3 weeks	✓
around 6 weeks	✓
around 12 weeks	✓
around 24 weeks	✓

Based on the evaluation of these tests your doctor will decide whether you should receive or continue using Valdoxan (see also under "How to take Valdoxan" in section 4).

Be vigilant about signs and symptoms that your liver may not be working properly

- **If you observe any of these signs and symptoms of liver problems: unusual darkening of the urine, light coloured stools, yellow skin/eyes, 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.**

Elderly patients

For depression: Effect of Valdoxan is not documented in patients aged 75 years and older. Valdoxan should therefore not be used in these patients.

For generalised anxiety disorder: Effect of Valdoxan is not documented in patients aged 65 years and older. Valdoxan should therefore not be used in these patients.

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Thoughts of suicide and worsening of your depression or anxiety

If you are depressed and/or have anxiety, 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 or have anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents

Valdoxan should not be used in children and adolescents (under 18 years old).

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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) can modify the expected dose of agomelatine in your blood.

Make sure to tell your doctor if you are taking any of the following medicines: propranolol (a beta-blocker used in the treatment of hypertension), enoxacin (antibiotic).

Make sure to tell your doctor if you are smoking more than 15 cigarettes/day.

How to take Valdoxan

Valdoxan is for oral use. You should swallow your tablet with a drink of water.

How much to take

For major depression and generalised anxiety disorder

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.

When to take it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Surveillance of the liver function (see also section 3):

Your doctor will run laboratory tests to check that your liver is working properly before starting treatment and then periodically during treatment, usually after 3 weeks, 6 weeks, 12 weeks and 24 weeks.

If your doctor increases the dose to 50mg, laboratory tests should be performed at this initiation and then periodically during treatment, usually after 3 weeks, 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.

How to switch from an antidepressant medicine (SSRI/SNRI) to Valdoxan?

If your doctor changes your previous antidepressant medicine from an SSRI or SNRI to Valdoxan, he/she will advise you on how you should discontinue your previous medicine when starting Valdoxan.

You may experience discontinuation symptoms related to stopping of your previous medicine for a few weeks, even if the dose of your previous antidepressant medicine is decreased gradually.

Discontinuation symptoms include: dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and shaking. These effects are usually mild to moderate and disappear spontaneously within a few days.

If Valdoxan is initiated while tapering the dosage of the previous medicine, possible discontinuation symptoms should not be confounded with a lack of early effect of Valdoxan.

You should discuss with your doctor on the best way of stopping your previous antidepressant medicine when starting Valdoxan.

How long to take it

Continue taking Valdoxan for as long as your doctor recommends.

Valdoxan starts to act on symptoms of depression and anxiety in most depressed people within two weeks of starting treatment.

Your depression and/or anxiety should be treated for a sufficient period of at least 6 months to ensure that you are free of symptoms.

Your doctor may continue to give you Valdoxan when you are feeling better to prevent your symptoms from returning.

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

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- *If you forget to take it*

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 take too much (overdose):*

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 stop using it*

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

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

While you are using Valdoxan

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Valdoxan.

Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

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

Do not take any new medicines without consulting your doctor.

Do not give Valdoxan to anyone else, even if they have the same symptoms or condition as you.

Valdoxan with food, drink and alcohol

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

- *Things to be careful of*
Driving and using machines

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

Valdoxan contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Valdoxan contains sodium

Valdoxan contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Side effects

Like all medicines, this medicine 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.

These side effects include:

- **Very common side effects** (may affect more than 1 in 10 people): headache
- **Common side effects** (may affect up to 1 in 10 people): dizziness, sleepiness (somnolence), difficulty in sleeping (insomnia), feeling sick (nausea), diarrhoea, constipation, abdominal pain, back pain, tiredness, anxiety, abnormal dreams, increased levels of liver enzymes in your blood, vomiting, weight increased.
- **Uncommon side effects** (may affect up to 1 in 100 people): migraine, pins and needles in the fingers and toes

(paraesthesia), blurred vision, restless leg syndrome (a disorder that is characterized by an uncontrollable urge to move the legs), ringing in the ears, excessive sweating (hyperhidrosis), eczema, pruritus, urticaria (hives), agitation, irritability, restlessness, aggressive behaviour, nightmares, mania/hypomania (See also under "Warnings and precautions" in section 3), suicidal thoughts or behaviour, confusion, weight decreased, muscle pain.

- **Rare side effects** (may affect up to 1 in 1,000 people): serious skin eruption (erythematous rash), face oedema (swelling) and angioedema (swelling of the face, lips, tongue and/or throat that may cause difficulty in breathing or swallowing), hepatitis, yellow coloration of the skin or the whites of the eyes (jaundice), hepatic failure*, hallucinations, inability to remain still (due to physical and mental unrest), inability to completely empty the bladder.

*few cases resulting in liver transplantation or death have been reported.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Valdoxan

- **Storage**

Keep this medicine out of the sight and reach of children.

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

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Store below 30°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Valdoxan 25 mg film-coated tablets (tablet) are oblong, orange-yellow

Valdoxan 25 mg film-coated tablets are available in calendar blisters. Packs contain 28 film-coated tablets.

- Ingredients

- Active ingredients: agomelatine.
Each tablet contains 25 mg of agomelatine.

- Other ingredients:

Lactose monohydrate, maize starch, povidone (K30), sodium starch glycolate type A, stearic acid, magnesium stearate, colloidal anhydrous silica, hypromellose, glycerol, macrogol (6000), yellow iron oxide (E172) and titanium dioxide (E171).

MAL number

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Product Registration Holder

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