

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, health care provider or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Valdoxan 25 mg

film-coated tablets Agomelatine

1. What Valdoxan is and what it is used for
2. Before you take Valdoxan
3. How to take Valdoxan

1. What Valdoxan is and what it is used for

Valdoxan contains the active ingredient agomelatine. It belongs to a group of medicines called antidepressants and you have been given Valdoxan to treat your depression.

Valdoxan is used in adults.

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.

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

2. Before you take Valdoxan

a. Do not take Valdoxan

- if you are allergic to agomelatine or any of the other ingredients of this medicine (listed in section 6).
- **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).

b. Take special care with Valdoxan

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

- If you are taking medicines known to affect the liver. Ask your doctor or health care provider for advice on which medicine that is.
- If you are obese or overweight, ask your doctor or health care provider for advice.
- If you are diabetic, ask your doctor or health care provider for advice.
- If you have increased levels of liver enzymes before treatment, your doctor or your health care provider 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 or health care provider before you

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start taking this medicine or before you continue with this medicine (see also under "Possible side effects" in section 4).

- If you are suffering from dementia, your doctor or health care provider will make an individual evaluation of whether it is right for you to take Valdoxan.

During your treatment with Valdoxan:

What to do to avoid potential serious liver problems

- Your doctor or health care provider 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:

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

Based on the evaluation of these tests your doctor or health care provider will decide whether you should receive or continue using Valdoxan (see also under "How to take Valdoxan" in section 3).

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 or health care provider who may advise you to stop taking Valdoxan.

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

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 health care provider 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.

Children and adolescents

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

▶ c. Taking other medicines, herbal or dietary supplements

Tell your doctor, health care provider 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 or health care provider if you are taking any of the following medicines: propranolol (a beta-blocker used in the treatment of hypertension), enoxacin (antibiotic) and if you are smoking more than 15 cigarettes/day.

▶ d. Taking Valdoxan with food and drink

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

▶ e. Pregnancy and breast-feeding

Pregnancy

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

Breast-feeding

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

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

▶ f. 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.

▶ g. Important information about some of the ingredients of Valdoxan

Valdoxan contains lactose

If you have been told by your doctor or health care provider that you have an intolerance to some sugars, talk to your doctor or health care provider before taking Valdoxan.

3. How to take Valdoxan

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

The recommended dose of Valdoxan is one tablet (25 mg) at bedtime. In some cases, your doctor or health care provider 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 or health care provider may continue to give you Valdoxan when you are feeling better to prevent your depression from returning.

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

Do not stop taking your medicine without the advice of your doctor or health care provider 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.

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

If your doctor or health care provider 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 or health care provider on the best way of stopping your previous antidepressant medicine when starting Valdoxan.

Surveillance of the liver function (see also section 2):

Your doctor or health care provider 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 or health care provider increase 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 or health care provider finds it necessary.

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

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

► **a. 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 or health care provider 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.

► **b. 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.

► **c. If you stop taking Valdoxan**

You should discuss with your doctor or health care provider before stopping this medicine.

If you think that the effect of Valdoxan is too strong or too weak, talk to your doctor, health care provider or pharmacist.

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

4. Possible 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 legs 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 2), suicidal thoughts or behaviour, confusion, weight decreased.
- **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.

Reporting of side effects

If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valdoxan

Keep this medicine out of the sight and reach of children. Store below 30°C, store in the original carton.

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.

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 to protect the environment.

6. Further information

► **a. What Valdoxan contains**

- The active substance is agomelatine. Each film-coated tablet contains 25 mg of agomelatine.
- The other ingredients are:
 - lactose monohydrate, maize starch, povidone, sodium starch glycolate type A, stearic acid, magnesium stearate, colloidal anhydrous silica, hypromellose, glycerol, macrogol, yellow iron oxide (E172) and titanium dioxide (E171).
 - printing ink : shellac, propylene glycol and indigotine (E132) aluminium lake

► **b. 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 tablets.

Not all pack sizes may be marketed.

► **c. Marketing Authorisation Holder and Manufacturer:**

Marketing Authorisation Holder

 Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex – France

Manufacturer

Les Laboratoires Servier Industrie
905, route de Saran
45520 Gidy – France

Or

Servier (Ireland) Industries Ltd
Gorey road
Arklow – Co. Wicklow – Ireland

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

► **d. This leaflet was last revised in: 11.2016**

► **e. Council of Arab Health Ministers:**

This is a Medicament
<ul style="list-style-type: none">• Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.• Follow the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.• The doctor and the pharmacist are the experts in medicines, their benefits and risks.• Do not by yourselves interrupt the period of treatment prescribed for you.• Do not repeat the same prescription without consulting your doctor.• Keep all medicaments out of reach of children
Council of Arab Health Ministers Union of Arab Pharmacists