

Package leaflet: Information for the patient

Valdoxan 25 mg film-coated tablets Agomelatine

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Valdoxan is and what it is used for
2. What you need to know before you take Valdoxan
3. How to take Valdoxan
4. Possible side effects
5. How to store Valdoxan
6. Contents of the pack and other information

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. What you need to know before you take Valdoxan

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).

Warnings and precautions

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 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 “Possible side effects” in section 4).
- If you are suffering from dementia, your doctor 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 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 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 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 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).

Other medicines and Valdoxan

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) and if you are smoking more than 15 cigarettes/day.

Valdoxan with alcohol

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

Pregnancy

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.

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.

Valdoxan 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 this medicine exactly as your doctor or pharmacist has told you. 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.

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 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 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.

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

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 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 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 stop taking Valdoxan

You should discuss with your doctor before stopping this medicine.

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

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, 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 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 listed in [Appendix V](#). 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.

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.

This medicine does not require any special storage conditions.

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. Contents of the pack and other information

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

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

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

Manufacturer

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

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

Anpharm Przedsiębiorstwo Farmaceutyczne S.A.
03-236 Warszawa
ul. Annopol 6B
Poland

Laboratorios Servier, S.L.
Avda. de los Madroños, 33
28043 Madrid
Spain

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

België/Belgique/Belgien

S.A. Servier Benelux N.V.
Tel: +32 (0)2 529 43 11

Lietuva

UAB “SERVIER PHARMA”
Tel: +370 (5) 2 63 86 28

България

Сервие Медикал ЕООД
Тел.: +359 2 921 57 00

Luxembourg/Luxemburg

S.A. Servier Benelux N.V.
Tel: +32 (0)2 529 43 11

Česká republika

Servier s.r.o.
Tel: +420 222 118 111

Danmark

Servier Danmark A/S
Tlf: +45 36 44 22 60

Deutschland

Servier Deutschland GmbH
Tel: +49 (0)89 57095 01

Eesti

Servier Laboratories OÜ
Tel: +372 664 5040

Ελλάδα

ΣΕΡΒΙΕ ΕΛΛΑΣ ΦΑΡΜΑΚΕΥΤΙΚΗ ΕΠΕ
Τηλ: +30 210 939 1000

España

Laboratorios Servier S.L.
Tel: +34 91 748 96 30

France

Les Laboratoires Servier
Tel: +33 (0)1 55 72 60 00

Hrvatska

Servier Pharma, d. o. o.
Tel.: +385 (0)1 3016 222

Ireland

Servier Laboratories (Ireland) Ltd.
Tel: +353 (0)1 663 8110

Ísland

Servier Laboratories
c/o Icepharma hf
Sími: +354 540 8000

Italia

Servier Italia S.p.A.
Tel: +39 06 669081

Κύπρος

C.A. Papaellinas Ltd.
Τηλ: +357 22741741

Latvija

SIA Servier Latvia

Magyarország

Servier Hungaria Kft.
Tel: +36 1 238 7799

Malta

GALEPHARMA Ltd
Tel: +(356) 21 247 082

Nederland

Servier Nederland Farma B.V.
Tel: +31 (0)71 5246700

Norge

Servier Danmark A/S
Tlf: +45 36 44 22 60

Österreich

Servier Austria GmbH
Tel: +43 (1) 524 39 99

Polska

Servier Polska Sp. z o.o.
Tel: +48 (0) 22 594 90 00

Portugal

Servier Portugal, Lda
Tel.: +351 21 312 20 00

România

Servier Pharma SRL
Tel: +4 021 528 52 80

Slovenija

Servier Pharma d. o. o.
Tel.: +386 (0)1 563 48 11

Slovenská republika

Servier Slovensko spol. s r.o.
Tel.: +421 (0) 2 5920 41 11

Suomi/Finland

Servier Finland Oy
P. /Tel: +358 (0)9 279 80 80

Sverige

Servier Sverige AB
Tel : +46 (0)8 522 508 00

United Kingdom

Servier Laboratories Ltd

Tel: +371 67502039

Tel: +44 (0)1753 666409

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