

VALDOXAN® 25mg

Agomelatine (pronounced a-go-mel-a-tin)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about VALDOXAN. It does not contain all the available information. You can obtain more information about VALDOXAN by talking to your doctor or pharmacist.

All medications have risks and benefits. Your doctor has weighed the risks of you taking VALDOXAN against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

You may need to read it again.

WHAT VALDOXAN IS USED FOR

VALDOXAN is used in the treatment of depression or to help prevent depression returning, and is only available with a doctor's prescription. The symptoms of depression vary from one person to another, but commonly include persistent sadness, loss of interest in favourite activities, feelings of worthlessness, sleep problems, feeling of being slowed down, feelings of anxiety or changes in appetite and weight. Changes in your daily sleep and appetite patterns are examples of disturbances of your 'body clock' that occur commonly in depression.

VALDOXAN can help regulate your 'body clock' (circadian rhythm) with

positive benefits on mood and sleep in depression.

VALDOXAN is not addictive.

VALDOXAN does not cause discontinuation symptoms and can be stopped without the need to taper dose.

In clinical studies VALDOXAN had no effect on sexual function.

VALDOXAN is not recommended for children, adolescents (under 18 years old) or elderly patients aged 75 or older.

Your doctor may prescribe VALDOXAN for another purpose. Ask your doctor if you have any questions about why VALDOXAN has been prescribed for you.

BEFORE YOU TAKE VALDOXAN

There are some people who shouldn't take VALDOXAN. Please read the list below. If you think any of these situations apply to you or you have any questions, please see your doctor.

When you must not take VALDOXAN

- **Do not take VALDOXAN if:**
- **you suffer from liver disease or you know your liver does not work properly (hepatic impairment)**
- **routine blood tests show levels of liver enzymes have increased to more than 3 times the upper limit of normal**

- **you are currently taking fluvoxamine (a drug used in the treatment of depression) or ciprofloxacin (an antibiotic used to treat infections)**
- **you have an allergy to VALDOXAN or any of the ingredients (including lactose) listed at the end of this leaflet**
- **the packaging is torn or shows signs of tampering**
- **the expiry date (EXP) printed on the pack has passed.**

Before you start to take VALDOXAN

A routine blood test should be performed before treatment to check how your liver is functioning. If you have increased levels of liver enzymes your doctor will decide if VALDOXAN is right for you.

You may be at risk of liver problems if you are overweight, obese or have diabetes or if you are taking medicines known to affect your liver (ask your doctor if you are unsure which medicines these might be).

Tell your doctor if you have ever experienced or develop an episode of bipolar disorder, mania or hypomania (extreme upward mood swings or irritable mood).

Your doctor should be made aware if you have a history of dementia.

Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding.

Talk to your doctor about how much alcohol you drink. People who drink excessive quantities of alcohol should not take

VALDOXAN. Excessive alcohol may cause liver problems and may make depression worse.

Tell your doctor if you are smoking more than 15 cigarettes/day.

If you have any doubts or questions about taking VALDOXAN consult with your doctor.

Taking other medications

Tell your doctor if you are taking any other medications, including medications you buy without a prescription from a pharmacy, supermarket, health food shop or naturopath/herbalist.

Tell your doctor if you are taking propranolol (a medicine sometimes used to treat heart problems).

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.

Swallow VALDOXAN tablets whole with some water in the evening at bedtime.

VALDOXAN can be taken with or without food.

How much to take

The usual dose of VALDOXAN is one tablet in the evening at bedtime. In some cases your doctor may prescribe two tablets (50 mg) to be taken together in the evening at bedtime. You should not take more than the maximum recommended dose of 50 mg daily.

Do not change your dose without the advice of your doctor even if you feel better.

How long to take it

Current experience with medications to treat depression shows that treatment for six

months or longer provides the best opportunity of long-term recovery from a first episode of depression. For those who have previously had depression, a longer period of treatment will usually be recommended.

With VALDOXAN, some people experience improvements in mood and sleep within two weeks of starting treatment. As people respond differently to medications, do not become discouraged if you do not notice a difference right away.

Continue taking VALDOXAN until your doctor advises you to stop. Even when you are feeling better, your doctor would usually continue to give you VALDOXAN for some time to help to prevent your depression from returning.

When you and your doctor have decided to stop VALDOXAN, there is no need to taper the dose as VALDOXAN does not cause discontinuation symptoms after stopping treatment.

If you forget to take it

If you forget to take your VALDOXAN skip the dose you missed, take your next planned dose at the usual time and continue as normal.

To avoid confusion, it is recommended that you leave the tablet you missed in the tablet strip and continue on with the next day's tablet as indicated on the tablet strip calendar.

Do not try to make up for missed doses. Simply take one dose per day.

The calendar printed on the tablet strip should help you remember when you last took a VALDOXAN tablet. It is also a good reminder of how much VALDOXAN you have left so you can get your prescription refilled if you need to.

If you take too much (overdose)

It is important that you do not take more VALDOXAN tablets than your doctor has prescribed.

The experience of overdoses with VALDOXAN is limited but reported symptoms include stomach pain, drowsiness, tiredness, agitation, anxiety, dizziness, blue-ish discolouration of the skin or mucous membranes and/or a general feeling of being unwell.

If you do take more than you have been prescribed, contact your doctor immediately for advice.

If anyone accidentally swallows any of your VALDOXAN tablets, call your nearest Poisons Information Centre for advice (Australian telephone: 13 11 26), or go to Accident and Emergency at your nearest hospital. Keep the telephone number for these places handy whilst taking any medications.

WHILE YOU ARE TAKING VALDOXAN

Your liver function

VALDOXAN is processed by the liver. Before you started taking VALDOXAN a blood test was required to check your liver function. While you are taking VALDOXAN you will need further blood tests to check your liver continues to function properly. These tests should be performed:

- before the start of treatment and before a dose increase to 50mg (dose should only be increased by your doctor).

and then around:

- 3 weeks,
- 6 weeks,
- 12 weeks and
- 24 weeks.

These blood test results will help your doctor decide whether

VALDOXAN is suitable for you. VALDOXAN may sometimes affect the results of these blood tests.

You may also have tests to check that your liver is working properly if you start to take medicines that interfere with how the body processes VALDOXAN.

Talk to your doctor about how much alcohol you drink.

Things you must do

To make sure you have the best opportunity of long-term recovery from your depression, continue to take VALDOXAN as long as your doctor recommends you to.

Tell your doctor if you have experienced or develop an episode of bipolar disorder, mania or hypomania (extreme upward mood swings or irritable mood).

Check with your doctor that your liver function tests are done as described in the YOUR LIVER FUNCTION section above.

Seek advice from your doctor immediately if you develop signs or symptoms of potential liver problems (such as dark urine, light coloured faeces, yellow skin or eyes, pain in your upper right abdomen, new-onset and unexplained fatigue). Your doctor may advise you to stop taking VALDOXAN.

Tell your doctor immediately if you become pregnant while taking VALDOXAN.

Tell all doctors, dentists and healthcare professionals who are treating you that you are taking VALDOXAN.

Do not take any other medications, whether they require a prescription or not, without first telling your doctor that you are taking VALDOXAN as sometimes the action of one medicine may interfere with another.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was

not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Keep all of your doctor's appointments so that your progress can be checked.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

If you have any thoughts about suicide or doing harm to yourself call your doctor immediately and also contact someone you trust.

All thoughts or talk about suicide or violence towards others or yourself are serious. Such thoughts may even occur after commencing antidepressant treatment, particularly before the full antidepressant effect is seen. Such thoughts are more likely to occur in young adults under 25 years of age.

If you or someone you know is showing any of the following common warning signs, either contact your doctor or healthcare professional or go to the nearest hospital for treatment:

- worsening of your depression
- thoughts or talk about death or suicide
- thoughts or talk about self-harm or doing harm to others
- any recent attempts of self-harm
- an increase in aggressive behaviour, irritability or agitation.

In addition to talking to your doctor, confidential support and counselling services are available (in Australia) from LifeLine by calling 13 11 14.

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.

Things you must not do

You should not take VALDOXAN together with certain medications (see also under "When you must not take VALDOXAN") such as: fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).

Do not give this medicine to anyone else even if their symptoms seem similar to yours or if they have the same condition as you.

Things to be careful of

As with all medications used to treat depression, you should make sure that you know how you react to VALDOXAN before you drive or operate machinery. Speak to your doctor if you have any concerns.

It is recommended to avoid drinking alcohol while taking any antidepressant including VALDOXAN.

UNWANTED EFFECTS POTENTIALLY DUE TO TREATMENT AND/OR YOUR DEPRESSION

Tell your doctor or pharmacist or go to the nearest Accident and Emergency at the nearest hospital as soon as possible if you do not feel well while you are taking VALDOXAN.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

The possibility of a severe liver reaction exists, especially with excessive alcohol consumption and/or with any other medication processed by the liver, e.g. VALDOXAN. Symptoms of severe liver reactions may include:

- yellow colouring of the skin or whites of the eyes (jaundice)

- **abnormal bleeding or bruising**
- **confusion, loss of consciousness or hallucinations.**

The possibility of a severe allergic reaction exists with any medication. The following are general signs and symptoms of an allergic reaction:

- **itching, skin rash or hives**
- **shortness of breath, wheezing or trouble breathing**
- **swelling of the face, lips, tongue or other parts of the body which may cause difficulty in swallowing or breathing.**

Severe liver reactions and severe allergic reactions are very serious. Medical attention or hospitalisation may be required and should be sought urgently from a doctor or Accident and Emergency at the nearest hospital.

VALDOXAN has been developed to treat people with depression and is usually well tolerated, however all medications may have unwanted effects in some people.

Increases in liver enzymes, and rarely inflammation of the liver, have been observed in some patients treated with VALDOXAN. When VALDOXAN was discontinued in these patients, the increases in liver enzymes usually returned to normal levels. This is why your doctor has asked you to have routine blood tests.

Some people taking VALDOXAN for depression have reported the following adverse reactions, which may relate to their depression, general health or any of their treatments:

Very common side effects (may affect more than 1 in 10 people):

- headache

Common side effects (may affect up to 1 in 10 people):

- sleepiness (somnolence), difficulty in sleeping (insomnia)
- dizziness, abnormal dreams

- feeling sick (nausea), diarrhoea, constipation, abdominal pain, vomiting
- back pain
- tiredness
- anxiety
- increased levels of liver enzymes in your blood
- weight increased.

Uncommon side effects (may affect up to 1 in 100 people):

- mania/hypomania (see also under 'Before you start to take VALDOXAN')
- suicidal thoughts or behaviour
- migraine
- pins and needles in the fingers and toes (paraesthesia), restless legs syndrome (a disorder that is characterised by an uncontrollable urge to move the legs)
- blurred vision
- ringing in the ears
- excessive sweating (hyperhidrosis).
- eczema, pruritus, urticaria (hives)
- agitation, irritability, restlessness, aggressive behaviour
- nightmares
- 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 (isolated cases of death or liver transplantation have been reported in patients with hepatic risk factors)
- hallucinations

- inability to remain still (due to physical and mental unrest)
- inability to completely empty the bladder.

Do not be alarmed, you may not experience any of these. Other unwanted effects have been uncommonly reported and you should ask your doctor or pharmacist if you want to know more.

See your doctor if you experience any of these or notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand something in this list.

AFTER TAKING VALDOXAN

Storage

Keep your tablets in the pack until it is time to take them. Keep them in a cool, dry place where it stays below 30°C. Keep them where children cannot reach them.

Disposal

If your doctor tells you to stop taking VALDOXAN, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

Product description

VALDOXAN is registered on the Australian register of Therapeutic Goods and has the Australian Register number: AUST R 159712.

What it looks like

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

VALDOXAN 25 mg tablets are contained in a foil blister strip with a calendar printed on the blister to help you remember when you last took a tablet of VALDOXAN.

Ingredients

Each film-coated tablet of VALDOXAN contains 25 mg of agomelatine as the active ingredient and the following inactive ingredients: lactose monohydrate, maize starch, povidone, sodium starch glycollate, stearic acid, magnesium stearate, colloidal anhydrous silica, hypromellose, iron oxide yellow, glycerol, macrogol 6000 and titanium dioxide, shellac, indigo carmine and propylene glycol.

VALDOXAN contains sugars as lactose.

Manufacturer/Sponsor

VALDOXAN is a product discovered by Servier Research International.

It is distributed in Australia by:

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