VALOMEL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VALOMEL?

VALOMEL contains the active ingredient agomelatine. VALOMEL is used for the treatment of depression and the prevention of relapse of depression. For more information, see Section 1. Why am I using VALOMEL? in the full CMI.

2. What should I know before I use VALOMEL?

Do not use if you have ever had an allergic reaction to VALOMEL or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. Do not use VALOMEL if you suffer from liver disease or you know your liver does not work properly (hepatic impairment). For more information, see Section 2. What should I know before I use VALOMEL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VALOMEL and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use VALOMEL?

- The usual dose is one tablet at bedtime. In some cases, your doctor may prescribe two tablets (50 mg) taken together at bedtime.
- You should not take more than the maximum recommended dose of two tablets daily. Do not change your dose without the advice of your doctor even if you feel better.

More instructions can be found in Section 4. How do I use VALOMEL? in the full CMI.

5. What should I know while using VALOMEL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using VALOMEL. • Have blood tests to check your liver function before the start of treatment and before a dose increase to 50 mg (dose should only be increased by your doctor), and then around: 3, 6, 12 and 24 weeks.
Things you should not do	• You should not take VALOMEL together with certain medications such as: fluvoxamine (another medicine used in the treatment of depression) or ciprofloxacin (an antibiotic).
Driving or using machines	• As with all medications used to treat depression, you should make sure that you know how you react to VALOMEL before you drive or operate machinery.
Drinking alcohol	• It is recommended to avoid drinking alcohol while taking any antidepressant including VALOMEL. • People who drink excessive quantities of alcohol should not take VALOMEL. Excessive alcohol may cause liver problems and may make depression worse.
Looking after your medicine	• Keep your tablets in the pack until it is time to take them. Keep them in a cool, dry place where it stays below 25°C. Keep them where children cannot reach them.

For more information, see Section 5. What should I know while using VALOMEL? in the full CMI.

6. Are there any side effects?

VALOMEL is usually well tolerated, however all medications may have unwanted effects in some people. Most side effects are minor and temporary. However, some may need medical attention. Severe liver reactions (especially with excessive alcohol consumption and/or with any other medication processed by your liver) and severe allergic reactions have very rarely been reported. Medical attention or hospitalisation may then be required and should be sought urgently from a doctor or Accident and Emergency at the nearest hospital. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

VALOMEL®

Active ingredient(s): *Agomelatine (a-go-mel-a-tin)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VALOMEL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VALOMEL.**

Where to find information in this leaflet:

1. Why am I using VALOMEL?
2. What should I know before I use VALOMEL?
3. What if I am taking other medicines?
4. How do I use VALOMEL?
5. What should I know while using VALOMEL?
6. Are there any side effects?
7. Product details

1. Why am I using VALOMEL?

VALOMEL contains the active ingredient agomelatine.

VALOMEL is used in the treatment of depression and the prevention of relapse of depression.

The symptoms of depression vary from one person to another, but a depressive episode commonly includes 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.

VALOMEL can help regulate your 'body clock' (circadian rhythm) with positive benefits on mood and sleep in depression.

Your doctor may prescribe VALOMEL for another purpose other than the treatment of your depression.

Ask your doctor if you have any questions about why VALOMEL has been prescribed for you.

VALOMEL is not addictive.

VALOMEL does not cause discontinuation symptoms on stopping treatment and can be stopped without the need to taper dose.

In clinical studies VALOMEL had no effect on sexual function.

This medicine is not recommended for children, adolescents (under 18 years of age) or elderly patients aged 75 years or older.

2. What should I know before I use VALOMEL?

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

Warnings

Do not use VALOMEL if:

- you are allergic to agomelatine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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 medicine used in the treatment of depression) or ciprofloxacin (an antibiotic used to treat infections).
- you have an allergy to VALOMEL or any of the ingredients 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.

Check with your doctor if you:

Have any other medical conditions, especially liver disease, if you know your liver does not work properly, or if you have elevated liver enzyme levels, more than three times the upper limit of normal.

- Take any medicines for any other conditions, especially fluvoxamine, a medicine used to treat depression or ciprofloxacin, an antibiotic used to treat infection.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VALOMEL and affect how it works.

Medicines that may <u>increase</u> the effect of VALOMEL include:

- Fluvoxamine, a medicine used in the treatment of depression
- Ciprofloxacin, an antibiotic used to treat infections

- Propranolol, a medicine sometimes used to treat heart problems

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VALOMEL.

4. How do I use VALOMEL?

How much to use

Use VALOMEL exactly as your healthcare professional tells you.

The usual dose of VALOMEL 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.

When to take VALOMEL

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

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

VALOMEL can be taken with or without food

How long to use VALOMEL for

Current experience with VALOMEL to treat depression shows that treatment for at least six months or longer provides the best opportunity of long-term recovery. With VALOMEL some people may experience improvements within two to four 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 VALOMEL until your doctor advises you to stop. Even when you are feeling better, your doctor would usually continue to give you VALOMEL for some time to help to prevent your depression from returning.

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

If you forget to use VALOMEL

VALOMEL should be used regularly at the same time each day.

If you forget to take your VALOMEL, skip the dose you missed, take your next planned treatment at the usual dose and usual time, then continue as normal. Do not take a double dose to make up for the dose you missed.

If you use too much VALOMEL

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

If you think that you have used too much VALOMEL, you may need urgent medical attention.

The experience of overdoses with VALOMEL is limited but reported symptoms may 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.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VALOMEL?

Your liver function

VALOMEL is processed by the liver.

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).

Before you start taking VALOMEL a blood test is required to check your liver function. While you are taking VALOMEL 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 VALOMEL is suitable for you.

VALOMEL 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 VALOMEL.

Talk to your doctor about how much alcohol you drink.

Things you should do

To make sure you have the best opportunity of long-term recovery from your depression, continue to take VALOMEL 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 Section 2. What should I know before I use VALOMEL?

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 VALOMEL.

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

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

Do not take any other medications, whether they require a prescription or not, without first telling your doctor that you are taking VALOMEL 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.

Call your doctor straight away:

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 should not do

Do not stop taking this medicine suddenly.

You should not take VALOMEL together with certain medications (see also under Section 2. What should I know before I use VALOMEL? **and Section** 3. What if I am taking other medicines?**) 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.

Driving or using machines

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

Drinking alcohol

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

Tell your doctor if you drink alcohol. Talk to your doctor about how much alcohol you drink.

People who drink excessive quantities of alcohol should not take VALOMEL.

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store VALOMEL below 25°C and in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the medicine when the expiry date (EXP) printed on the pack has passed.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

VALOMEL 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 VALOMEL. When VALOMEL 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 VALOMEL have reported the following side effects, which may relate to VALOMEL, their depression, general health or to any of their other treatment(s).

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

Less serious side effects

Less serious side effects	What to do
Psychiatric disorders: • agitation, irritability, restlessness, aggressive behaviour • mania/hypomania (see also under 'Before you start to take VALOMEL') • suicidal thoughts or behaviour • nightmares • confusion • hallucinations • anxiety Nervous system disorders: • headache • migraine • dizziness, abnormal dreams • sleepiness (somnolence), difficulty in sleeping (insomnia) • 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) • inability to remain still (due to physical and mental unrest) Eye disorders: • blurred vision Ear disorders: • ringing in the ears Gastrointestinal Disorders: • feeling sick (nausea), diarrhoea, constipation, abdominal pain, vomiting Liver disorders: • increased levels of liver enzymes in your blood • 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) Skin and subcutaneous tissue disorders: • eczema, pruritus, urticaria (hives) • excessive sweating (hyperhidrosis) • 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) Musculoskeletal and connective tissue disorders: • back pain, muscle pain. Kidney and urinary disorders: • inability to completely empty the bladder. General disorders: • weight increased. • weight decreased • tiredness.	**Speak to your doctor if you have any of these less serious side effects.** **Ask your doctor or pharmacist if you do not understand something in this list.**

Serious side effects

Serious side effects	What to do
Severe liver reactions, especially with excessive alcohol consumption and/or with any other medication processed by the liver, e.g. VALOMEL. 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 **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	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
body which may cause difficulty in swallowing or breathing.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VALOMEL contains

Active ingredient (main ingredient)	Agomelatine
Other ingredients (inactive ingredients)	Silicified microcrystalline cellulose Mannitol Povidone Colloidal anhydrous silica Crospovidone Sodium stearyl fumarate Magnesium stearate Stearic acid Hypromellose Macrogol 6000 Purified talc Titanium dioxide(E171) Iron oxide yellow (E172)

Do not take this medicine if you are allergic to any of these ingredients.

What VALOMEL looks like

VALOMEL is a yellow, oblong, film-coated tablet (AUST R 381137).

VALOMEL comes in packs of 28 tablets.

Who distributes VALOMEL

Sponsor

Helix Pharmaceuticals

C\- EGA Corporate Advisors Pty Ltd

Level 12, 468 St Kilda Road,

Melbourne VIC 3044

Email: info@helixpharmaceuticals.com.au

Distributor

VALOMEL is distributed in Australia by:

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