

Agomelatine

Valdoxan • UK tablets: 25 mg

An antidepressant used outside the US. Liver testing is part of treatment, even when you feel well.

From Jeffrey Panko, PMHNP-BC's education collection ·

Draft for review · Clinical content has not been revalidated for this website.

NOT FDA-APPROVED

UK REFERENCE • KEEP EVERY LIVER-TEST APPOINTMENT

International reference only. Follow your local prescriber's plan; do not start or change treatment from this sheet.

What it is used for

The UK product treats major depressive episodes in adults. It is not an FDA-approved medicine.

It is not a general sleeping pill. Use for anxiety is outside the reviewed UK indication.

How it works

It acts at melatonin and serotonin receptors involved in body-clock and mood signaling. It is not an SSRI.

The contribution of each receptor is uncertain. No particular sleep or mood benefit is guaranteed.

What to expect over time

FIRST WEEKS

Sleep or daytime functioning may improve before mood. Headache, nausea or dizziness can occur early.

REVIEW AT TWO WEEKS

Your clinician reviews response and liver risk before considering a higher dose. Do not increase it yourself.

LONGER TERM

Effective treatment commonly continues for at least six months under UK guidance. Review duration together.

Taking your medication

UK dosing usually starts at 25 mg at bedtime, with or without food. A prescribed 50-mg dose means two 25-mg tablets taken together at bedtime.

Have liver tests before starting. Higher doses need a new monitoring schedule; liver disease may rule this medicine out entirely.

Avoid alcohol. If dizzy or sleepy, do not drive or use machinery. Check every new medicine with your pharmacist.

When to get help

Stop and seek urgent medical advice: dark urine, pale stools, yellow eyes/skin, upper-right belly pain or new persistent unexplained fatigue. These may signal liver injury.

Get prompt help: suicidal thoughts, worsening depression, racing thoughts, unusually risky behavior or much less need for sleep.

Call your local emergency number: immediate danger, collapse, seizure, inability to wake, or face/throat swelling with breathing trouble. Any overdose needs urgent advice.

Early side effects

Headache, nausea, dizziness, sleepiness, insomnia, diarrhea or constipation can occur. Discuss persistent effects; unexplained fatigue or belly pain needs liver assessment.

Other effects to discuss

Liver enzymes may rise without symptoms. Weight and sexual effects can occur. Do not skip blood tests because you feel well or assume this medicine has no sexual side effects.

What to keep track of

Liver tests: before treatment, then around weeks 3, 6, 12 and 24, and when needed. Repeat this schedule after a dose increase. Report liver symptoms immediately between tests.

Before you start

Discuss liver or kidney disease, alcohol use, fatty liver, diabetes, bipolar disorder, suicidal thoughts, pregnancy and breastfeeding. UK guidance advises against use below 18 or at 75 and older, and in older adults with dementia. Pregnancy or breastfeeding needs a treatment or feeding plan; limited evidence does not establish safety. Tell your clinician about rare inherited sugar disorders because this product contains lactose.

Medicines & interactions

Fluvoxamine or ciprofloxacin

Do not combine either medicine with agomelatine. They can sharply increase its level. Tell any clinician prescribing an antidepressant or antibiotic that you take agomelatine.

Other medicines and smoking

Check propranolol, estrogen-containing medicines, rifampin and all supplements. Starting or stopping smoking can change drug levels. Do not adjust the dose yourself.

Alcohol, liver risks and switching

Avoid alcohol and review medicines that can affect the liver. Switching from another antidepressant needs its own taper or washout plan; do not combine with an MAOI.

Everyday tips

Put liver-test dates in your calendar before the first tablet and after any dose increase.

Track mood, sleep, daytime function and adverse effects; bring the record to follow-up.

Ask someone you trust to tell you about marked mood or behavior changes, if that feels helpful.

Keep therapy, activity and a steady sleep routine in the plan. Medication is one part of treatment.

Your questions, answered

What if I miss a dose?

Skip it and take the next dose at the usual time. Never double to catch up.

Can I stop when I feel better?

Plan stopping with your clinician. Agomelatine itself generally needs no taper, but depression can return. Suspected liver injury is a reason to stop immediately and seek advice.

What if a liver test is abnormal?

Contact your clinician promptly. Raised enzymes may need repeat testing within 48 hours. Results above the stopping threshold require immediate discontinuation and follow-up tests.

Will it prevent withdrawal from my old medicine?

No. An SSRI or SNRI may still cause withdrawal during a switch. Follow that medicine's individualized taper; fluvoxamine must not overlap with agomelatine.

Storage & safety

Keep tablets secured from children and pets, in their labeled pack. Check the expiry date. Ask your pharmacist about disposal; do not share medicines.

A final reminder

not US prescribing instructions.

About this information

For general information only; not a substitute for individualized medical advice. This sheet does not cover every risk or interaction. Ask your prescriber or pharmacist before changing how you take this medication.

Sources

1. <https://www.medicines.org.uk/emc/product/6564/pil>
 2. <https://www.medicines.org.uk/emc/product/6564/smpc>
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Educational inclusion does not mean this medication or its indications are treated at this practice. Review the guide for your exact product with your prescriber or pharmacist.

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