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PATIENT EDUCATION

Agomelatine

Valdoxan / International oral formulations

A guide for adults taking agomelatine.
Follow the directions on your prescription and your provider's recommendations.

NOT FDA-APPROVED

UK REFERENCE · KEEP EVERY LIVER-TEST APPOINTMENT

Formulations: Oral tablets are taken at bedtime. The prescribed dose and liver-test schedule must be reviewed together, including after any dose increase.

What it is used for

Agomelatine treats major depression in adults in countries where it is approved. This guide describes the UK oral formulation; it is not a routine U.S. prescription option.

How it works

It activates melatonin receptors involved in the sleep–wake cycle and blocks a serotonin receptor called 5-HT2C. These actions influence circadian rhythms and signaling related to mood.

What to expect over time

Sleep, energy, or appetite may change before mood improves. Benefit usually builds over several weeks; some conditions need a longer trial at a useful dose.

Track the symptoms you are treating and how you manage daily activities. Keep follow-up appointments. Schedule an earlier appointment if your mood gets worse.

Taking your medication

- Take at bedtime, with or without food, following your prescription.
- If you miss a dose, take it when you remember unless it is almost time for the next dose. Then skip it. Do not double a dose.
- Avoid alcohol because of the risk to your liver. Do not increase the dose yourself.

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Side effects and safety

Possible side effects

- Headache or dizziness
- Nausea or abdominal discomfort
- Sleep changes or fatigue

Keeping track of treatment

Some side effects resolve with time; others may require a change of medication. Discuss persistent or bothersome side effects with your provider.

Liver tests are needed before treatment and at about 3, 6, 12, and 24 weeks, with additional tests when indicated. The monitoring schedule restarts after a dose increase.

Track mood and sleep. Keep laboratory visits even when you feel well; liver changes may have no early symptoms.

If you take too much

For a suspected overdose, call Poison Control at **1-800-222-1222** immediately, even if you feel well. Call 911 for a seizure, collapse, trouble breathing, or inability to wake.

Before you start

Do not take with liver disease or substantially elevated liver enzymes. Discuss alcohol use, diabetes, excess weight, and all medicines that affect the liver. UK labeling advises against use at age 75 or older.

Discuss pregnancy, pregnancy plans, and breastfeeding with your provider. Treatment decisions should consider both the medication and the condition being treated.

Medicines and interactions

Review all your medications with your provider, including over-the-counter medicines and supplements. Have new medications checked before taking them.

Do not combine with fluvoxamine or ciprofloxacin; they can greatly increase agomelatine exposure. Other medicines that affect its breakdown also require review.

Tell your provider about changes in smoking, estrogen therapy, and medicines that can injure the liver.

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Living with your treatment

When to get help

Emergency symptoms. Get emergency care for a severe allergic reaction, collapse, or a seizure.

Prompt medical advice. Stop agomelatine and obtain prompt medical advice for yellow skin or eyes, dark urine, pale stools, right upper abdominal pain, or new unexplained persistent fatigue. These may indicate liver injury.

If you feel unsafe or have thoughts of self-harm, call 911 or go to an emergency department.

Your questions answered

Do I need a taper?
Agomelatine itself generally does not require tapering, but consult with your provider before stopping. A different antidepressant used during a switch may still need a gradual reduction.

Can I skip blood tests if I feel well?
No. Liver injury may begin without noticeable symptoms. The tests are part of treatment.

Everyday tips

A regular dose time and refill reminder can help prevent missed doses.

Bring a few specific observations to appointments: sleep, motivation, anxiety, and activities that have become easier or harder.

Storage and safety

Keep medication in its labeled container, away from excess heat and moisture and out of reach of children and pets. Do not share it. Ask a pharmacy about disposal of unused medication.

Sources

UK prescribing information: Valdoxan (updated 2026)

Educational handout; does not replace your prescription or provider's recommendations.