

Agomelatine – Prescribing and Monitoring in Adults: Information for Primary Care

This document refers to Agomelatine when prescribed at a licensed dose for licensed indications. Agomelatine is licensed for the treatment of depression only (in those > 18 years of age), following a lack of response to a trial of at least three alternative antidepressant drugs at adequate doses and has a **GREEN PLUS** formulary status

Initial Prescribing and Monitoring – Secondary Care – Specialist Services

- ✓ Prescribe Agomelatine & perform a clinical review at 6 months to assess & decide on the need to continue treatment
- ✓ Specialist will perform liver function tests (LFT) in all patients receiving Agomelatine:-
 - On initiation of treatment (baseline)
 - At weeks 3, 6, 12 and 24 and when clinically indicated
 - After increasing the dose of Agomelatine (at the same time intervals as for initiation)
- ✓ Manage hepatotoxicity as appropriate in line with SPC (Appendix A)
- ✓ Provide patients with a **'Patient Alert Card'** (Appendix B), inform patients of the importance of liver function tests & how to recognise liver injury
- ✓ If appropriate to continue, a request can be made to GP, via a letter, to take over responsibility for ongoing prescribing and monitoring. This letter must include a completed copy of the **'Liver Function Monitoring Scheme'** (Appendix C)

Transfer at around 6 months / when LFT monitoring completed following dose increase.

Ongoing Prescribing and Monitoring – Primary Care – GP

- ✓ Continue to prescribe treatment following clinical review and request by specialist (at around 6 months)
- ✓ Opportunistically reiterate advice to patients about recognising signs of potential liver injury (Appendix B)
- ✓ Be vigilant for signs of liver damage. Routine LFT monitoring is not required beyond 24 weeks after initiation or dose increase; check LFTs only if there are signs or symptoms of liver damage or concerns about previous results (see Appendix C for more information)
- ✓ Manage hepatotoxicity as appropriate and in line with SPC (Appendix C); communicate discontinuation to specialist and seek advice on next treatment options
- ✓ Seek advice from Mental Health Specialist if there is increased concern about a patient's mental health

Important Points to Note for ALL Prescribers

- A patient who develops increased serum transaminases should have their liver function tests **REPEATED** within 48 hours
- Advise patients to **STOP** taking Agomelatine immediately and to seek urgent medical advice if signs of potential liver injury appear
- Agomelatine should be **IMMEDIATELY** discontinued if an increase in serum transaminases exceeds 3 x Upper Limit of Normal or if a patient presents with symptoms or signs of potential liver injury, such as dark urine, pale stools, jaundice, pain in right upper abdomen or sustained new-onset unexplained fatigue
- Agomelatine is **CONTRAINDICATED** with concomitant use of potent CYP1A2 inhibitors (e.g. Fluvoxamine and Ciprofloxacin)
- All suspected adverse reactions should be reported via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard
- Refer to the manufacturer's (Valdoxan®) 'Prescribing Guide' (Appendix C) for further Information*
- At each clinical review, consider the opportunity for deprescribing – seek specialist advice as necessary

Contact

For any concerns regarding treatment with agomelatine please use contact the local community treatment team using details provided in the most recent clinic letter or on the relevant Trust websites:

CNTW: <https://www.cntw.nhs.uk/services/>

TEWV: <https://www.tewv.nhs.uk/services/>

For general medication advice concerning agomelatine, the pharmacy medicines information service can be contacted at:

CNTW: medinfo@cntw.nhs.uk

TEWV: tewv.medicinesinformation@nhs.net

References

1. MHRA Drug Safety Update: Volume 8, Issue 4 November 2014
2. SPC of Valdoxan[®] – available at [Valdoxan 25 mg film-coated tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)
3. e BNF – Agomelatine – Accessed 05/04/2023 - [MedicinesComplete — CONTENT > BNF > Drug: Agomelatine](#)
4. NICE Guideline 222 – Depression in Adults: Treatment and Management – June 2022

Appendix A: Liver Function Monitoring Scheme (Valdoxan[®]) *

<https://www.medicines.org.uk/emc/rmm/67/Document>

Appendix B: Patient Alert Card (Valdoxan[®]) *

<https://www.medicines.org.uk/emc/rmm/68/Document>

Appendix C: Prescriber Guide (Valdoxan[®]) *

<https://www.medicines.org.uk/emc/rmm/64/Document>

*Agomelatine is now available as an unbranded, generic product – all generic manufacturers provide educational risk minimisation materials, adhering to a similar format/content as those provided by original manufacturer of Valdoxan. These materials can be accessed through [Home - electronic medicines compendium \(emc\)](#) if needed.

