NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

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 for at least three alternative antidepressant drugs at adequate doses and has an **AMBER** 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 in all patients receiving Agomelatine:-
  - On initiation of treatment (baseline)
  - At weeks 3, 6, 12 and 24 and when clinically indicated
  - When increasing the dose of Agomelatine (at the same time intervals as on initiation)
- Manage toxicity 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
- Undertake physical health monitoring as advised by manufacturer i.e. perform liver function tests when clinically indicated and take appropriate action if necessary (Appendix c) [routine LFT monitoring is otherwise not required beyond 24 weeks after initiation or dose increase)
- Seek advice from Mental Health Specialist if there is increased concern about a patient's mental health
- Reiterate advice to patient as to how to recognise signs of potential liver injury (Appendix B)
- Manage hepatotoxicity as appropriate and in line with SPC (Appendix C) and communicate discontinuation to specialist for advice on next treatment options

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 manufacturers (Valdoxan©) 'Prescribing Guide' (Appendix C) for further Information*

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.

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

N.B. this document is to be used to support transfer of prescribing within the NYYS care group area of TEWV only. Transfer of prescribing within the DTVF care group area should be supported using the version on the Northern Treatment Advisory Group (NTAG) website - https://ntag.nhs.uk (and search "agomelatine")

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