North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

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 a GREEN PLUS 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

Ongoing Prescribing and Monitoring – Primary Care – GP

- Continue to prescribe treatment following clinical review 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)
- Seek advice from Mental Health Specialist if there is increased concern about a patients mental health
- Reiterate advice to patient as to how to recognise signs of potential liver injury (Appendix B)
- Manage toxicity as appropriate and in line with SPC (Appendix C) and communicate discontinuation to specialist

Important Points to Note for ALL Prescribers

- Any 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

References

1. MHRA Drug Safety Update: Volume 8, Issue 4 November 2014
2. SPC of Agomelatine – available at www.medicines.org.uk
3. BNF 78, September 2019 – March 2020
4. NICE Guideline CG90 – Depression in Adults: Recognition and Management – April 2018

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