

This bulletin is intended to accompany **Issue 33** of **Kent & Medway CCG Medicines Optimisation (MO)** newsletter, dated 28.04.22. Please send all medicines queries relating to the articles written to: kmccg.medicinesoptimisation@nhs.net

MHRA Drug Safety Update (March 2022)

Amiodarone (Cordarone X): reminder of risks of treatment and need for patient monitoring and supervision

Amiodarone has been associated with serious and potentially life-threatening side effects, particularly of the lung, liver, and thyroid gland. We remind healthcare professionals that patients should be supervised and reviewed regularly during treatment.

Advice for Practices:

- amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin, and peripheral nervous system
- review regularly patients on long-term amiodarone treatment – some of these reactions may be lifethreatening but onset can be delayed
- check liver and thyroid function before treatment, and at 6-monthly intervals; thyroid function should also be monitored for several months after discontinuation
- although routine lung imaging is not necessary in patients taking amiodarone long-term, make patients aware of the need to seek advice if they have new or worsening respiratory symptoms and consider using computerised tomography (CT) scans if pulmonary toxicity is suspected
- report suspected adverse drug reactions associated with amiodarone on a Yellow Card

Advice for Practices to give to patients and carers:

- amiodarone is used to treat serious heart conditions in which your heart beats unevenly or too fast
- always read the Patient Information Leaflet provided with your medicines and follow the advice on other medicines to avoid and what to do if you have a side effect
- your doctor may perform tests of your blood, lungs, heartbeat, and eyes before and during treatment – it's important to have these tests because they can identify if there's a problem
- stop taking amiodarone and see a doctor or go to a hospital straight away if you experience any of the following during treatment or in the period after stopping amiodarone: new or worsening shortness of breath or coughing that will not go away, yellowing of the skin or eyes (jaundice), feeling tired or sick, loss of appetite, stomach pain, or high temperature, weakness, weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in menstrual periods, swelling of the neck (goitre), nervousness, irritability, restlessness, or decreased concentration, your heartbeat becomes even more uneven or erratic, or becomes very slow, any loss of eyesight.

Metformin in pregnancy: study shows no safety concerns

A large study has shown no safety issues of concern relating to the use of metformin during pregnancy. The licence for metformin now reflects that it can be considered for use during pregnancy and the periconceptional phase as an addition or an alternative to insulin, if clinically needed. This is consistent with current clinical guidance.

Cladribine (Mavenclad): new advice to minimise risk of serious liver injury – HOSPITAL ONLY

Liver monitoring requirements for cladribine in the treatment of multiple sclerosis have been introduced following uncommon cases of serious liver injury.

COVID-19 vaccines and medicines: updates for March 2022

Recent information relating to COVID-19 vaccines and medicines that has been published since the February 2022 issue of Drug Safety Update, up to 11 March 2022.

Letters and medicine recalls sent to healthcare professionals in February 2022

A summary of recent letters, medicine recalls and notifications sent to healthcare professionals.