Apr 2024

Safety Alert

Citalopram/Escitalopram-Risk of QT prolongation

EDA performs label update to include the following:

Contraindications:

Generic Name is contraindicated in patients with known QT interval prolongation or congenital long QT syndrome Generic Name is contraindicated together with medicinal products that are known to prolong the QT interval

Warning & Precautions:

QT interval prolongation

Generic Name has been found to cause a dose-dependent prolongation of the QT interval. Cases of QT interval prolongation and ventricular arrhythmia including torsade de pointes have been reported during the post-marketing period, predominantly in patients of female gender, with hypokalaemia, or with pre-existing QT interval prolongation or other cardiac diseases.

Caution is advised in patients with significant bradycardia; or in patients with recent acute myocardial infarction or uncompensated heart failure.

Electrolyte disturbances such as hypokalaemia and hypomagnesaemia increase the risk for malignant arrhythmias and should be corrected before treatment with Generic name is started.

If patients with stable cardiac disease are treated, an ECG review should be considered before treatment is started. If signs of cardiac arrhythmia occur during treatment with Generic Name, the treatment should be withdrawn and an ECG should be performed.

Background:

Indication

Citalopram /Escitalopram used to treat depression. Citalopram /Escitalopram is in a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs). It works by increasing the amount of serotonin, a natural substance in the brain that helps maintain mental balance.

References:

MHRA (Click here)