

Safety Alert

July 2023

Rivastigmine and risk of QT prolongation and torsade de pointes

EDA performs label update to include the following:

4. CLINICAL PARTICULARS

4.4 Special warnings and precautions for use

QT prolongation and torsade de pointes Electrocardiogram QT prolongation may occur in patients treated with certain cholinesterase inhibitor products including rivastigmine. Rivastigmine may cause bradycardia which constitutes a risk factor in the occurrence of torsade de pointes, predominantly in patients with risk factors. Caution is advised in patients at higher risk of developing torsade de pointes; for example, those with uncompensated heart failure, recent myocardial infarction, bradyarrhythmias, a predisposition to hypokalaemia or hypomagnesemia, personal or family history of QT prolongation, or concomitant use with medicinal products known to induce QT prolongation and/or torsade de pointes. Clinical monitoring may also be required.

Background on the safety concerns

”Cellular mechanisms of Torsade de Pointes ”

Torsade de Pointes (TdP) is a life-threatening arrhythmia closely linked to abnormal cardiac repolarization. It has been demonstrated that cardiac ion channel alterations underlying cellular repolarization results in the phenotypic expression of long QT syndrome, which is closely associated with TdP.

Symptoms of Torsade de Pointes

TdP can come on without warning. You may suddenly feel your heart beating faster than normal, even when you're at rest. In some TdP episodes, you may feel light-headed and faint. In the most serious cases, TdP can cause cardiac arrest or sudden cardiac death.

It's also possible have an episode (or more than one) that resolves quickly. This type of ventricular tachycardia is known as “unsustained.” “Sustained” ventricular tachycardia interferes with the normal functioning of the heart.

References:

TGA ([Click here](#))