

Consumer Update

March 2022

Donepezil-QTc interval extension and Torsade de Pointes

EDA performs Label Update to include the following:

Warnings

Cases of QTc interval prolongation and torsade de pointes have been reported in the post -marketing setting with the use of donepezil.

Adverse effects

Newly included in the product information: Polymorphic ventricular tachycardia including torsade de pointes, prolonged QTc interval in the electrocardiogram.

Background:

Donepezil is a selective reversible acetylcholinesterase inhibitor which is indicated for the symptomatic treatment of mild to moderate Alzheimer's disease.

The risk of cholinergic effects on heart rate is already known. The product information includes a warning that cholinesterase inhibitors may have vagotonic effects on the heart rate (e.g., bradycardia) and that the potential for this effect in patients with sick sinus syndrome or other supraventricular excitation conditions, such as: B. sinoatrial or atrioventricular block, may be particularly important.

The latest changes to the product information for donepezil are the result of an evaluation of post—marketing data and the scientific literature. Reports of QTc interval extensions and torsade de pointes associated with donepezil use have been identified and assessed by the EMA. It was found that a causal relationship between donepezil and QTc interval extensions and Torsade de Pointes is at least a reasonable possibility. Since the assessment was primarily based on spontaneous reports of adverse events after marketing, the frequency is reported as unknown.

References: TGA ([Click here](#))