



Summary of Investigation Results

Rivastigmine

August 29, 2023

Non-proprietary name

Rivastigmine

Brand name (marketing authorization holder)

Exelon Patch 4.5 mg, 9 mg, 13.5 mg, 18 mg (Novartis Pharma K.K.), Rivastach Patches 4.5 mg, 9 mg, 13.5 mg, 18 mg (Ono Pharmaceutical Co., Ltd.), and the others

Japanese market launch

July 2011

Indications

Suppression of progression of symptoms of dementia in mild and moderate Alzheimer's dementia.

Summary of revisions

1. "Patients with prolonged QT or a history/family history of the disease" should be added to the "Patients with heart diseases including myocardial infarction, cardiac valvulopathy, and cardiomyopathy, electrolyte abnormalities (e.g., hypokalaemia), etc." section in the PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS (new instructions) or to the Important Precautions section (old Instructions).
2. "Prolonged QT" should be added to the "angina pectoris, myocardial infarction, bradycardia, atrioventricular block, sick sinus syndrome" section in the Clinically Significant Adverse Reactions.

Investigation results and background of the revision

Cases involving prolonged QT and torsade de pointes were evaluated. Cases for which a causal relationship between rivastigmine and prolonged QT was reasonably possible have been reported in Japan and overseas. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving electrocardiogram prolonged QT and torsade de pointes reported in Japan and overseas

A total of 11 cases have been reported in Japan to date (including 5 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported in Japan to date.

A total of 15 cases have been reported overseas to date (including 3 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).