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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of PRECAUTIONS

## Rivastigmine

August 29, 2023

### **Therapeutic category**

Other agents affecting central nervous system

### **Non-proprietary name**

Rivastigmine

### **Safety measure**

PRECAUTIONS should be revised.

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director-General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions):

Revised language is underlined.

Current	Revision
<p><b>Important Precautions</b></p> <p>Bradycardia, atrioventricular block, etc. may occur following administration of this drug. In particular, patients with heart disease (e.g., myocardial infarction, cardiac valvulopathy, cardiomyopathy), patients with electrolyte abnormalities (e.g., hypokalaemia), etc. should be carefully monitored to prevent them from developing serious arrhythmia.</p> <p><b>Adverse Reactions</b></p> <p><b>Clinically Significant Adverse Reactions</b></p> <p>Angina pectoris, myocardial infarction, bradycardia, atrioventricular block, sick sinus syndrome:</p> <p>Angina pectoris, myocardial infarction, bradycardia, atrioventricular block, <u>and</u> sick sinus syndrome may occur. In such cases, administration should be discontinued immediately and appropriate measures should be taken.</p>	<p><b>Important Precautions</b></p> <p>Bradycardia, atrioventricular block, <u>prolonged QT, torsade de pointes</u>, etc. may occur following administration of this drug. In particular, patients with heart disease (e.g., myocardial infarction, cardiac valvulopathy, cardiomyopathy), patients with electrolyte abnormalities (e.g., hypokalaemia), <u>patients with prolonged QT or a history/family history of the disease</u>, etc. should be carefully monitored to prevent them from developing serious arrhythmia.</p> <p><b>Adverse Reactions</b></p> <p><b>Clinically Significant Adverse Reactions</b></p> <p>Angina pectoris, myocardial infarction, bradycardia, atrioventricular block, sick sinus syndrome, <u>prolonged QT</u>:</p> <p>Angina pectoris, myocardial infarction, bradycardia, atrioventricular block, sick sinus syndrome, <u>and prolonged QT</u> may occur. In such cases, administration should be discontinued immediately and appropriate measures should be taken.</p>

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

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3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
 E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.</p> <p>Patients with heart disease including myocardial infarction, cardiac valvulopathy, and cardiomyopathy, electrolyte abnormalities (e.g., hypokalaemia), etc.</p> <p>Bradycardia, atrioventricular block, etc. may occur. Patients should be carefully monitored to prevent them from developing serious arrhythmia.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angina pectoris, myocardial infarction, bradycardia, atrioventricular block, sick sinus syndrome</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.</p> <p>Patients with heart disease including myocardial infarction, cardiac valvulopathy, and cardiomyopathy, electrolyte abnormalities (e.g., hypokalaemia), etc., <u>and patients with prolonged QT or a history/family history of the disease</u></p> <p>Bradycardia, atrioventricular block, <u>prolonged QT, torsade de pointes</u>, etc. may occur. Patients should be carefully monitored to prevent them from developing serious arrhythmia.</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Angina pectoris, myocardial infarction, bradycardia, atrioventricular block, sick sinus syndrome, <u>prolonged QT</u></p>

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