

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

Attachment 4
August 25, 2026

【Therapeutic category】 239 Other agents affecting digestive organs

【Non-proprietary name】 Metoclopramide

Metoclopramide hydrochloride

【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS N/A	8. IMPORTANT PRECAUTIONS <u>Increased risks of fatal arrhythmias have been suggested in Japanese epidemiological studies and those of sudden cardiac death have been suggested in Japanese and overseas epidemiological studies.</u> <u>Serious arrhythmias, including ventricular tachycardia and ventricular fibrillation, may occur. The following precautions should be observed:</u> <u>• Use should be limited to the minimum necessary, and prolonged treatment without periodic reassessment should be avoided.</u> <u>• Patients should be instructed to seek immediate medical attention if relevant symptoms occur.</u> <u>• Patients should be closely monitored, and if relevant symptoms occur, cardiac function tests (electrocardiography, etc.) should be performed immediately.</u>

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.

11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions N/A	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Serious arrhythmias</u> <u>Serious arrhythmias, including ventricular tachycardia and ventricular fibrillation, may occur. If any abnormalities are observed, appropriate measures including discontinuation of this drug, resuscitative measures, and defibrillation should be taken.</u>
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(Note) Drugs subject to preparation of Drug Guide for Patients should be specified.

[Reference] Summary of the results of the study using the NDB (risk assessment for the occurrence of fatal arrhythmia events induced by domperidone or metoclopramide):

N/A: Not Applicable. No corresponding description is included in the current PRECAUTIONS.

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