

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 3
August 25, 2026

【Therapeutic category】 239 Other agents affecting digestive organs

【Non-proprietary name】 Domperidone

【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 and 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>
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions

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N/A	<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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