

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.

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

Domperidone

May 20, 2025

Therapeutic category

Other agents affecting digestive organs

Non-proprietary name

Domperidone

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p><u>Pregnant women or women who may be pregnant</u></p>	<p>2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)</p> <p>(deleted)</p>
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p><u>This drug should not be administered to pregnant women or women who may be pregnant.</u> Teratogenic effects such as skeletal and visceral anomalies have been reported in animal studies (rats).</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p><u>Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks.</u> Teratogenic effects such as skeletal and visceral anomalies have been reported <u>at approximately 65 times the clinical dose (body surface area conversion)</u> in animal studies (rats).</p>