

Summary of Investigation Results

Domperidone and metoclopramide hydrochloride/metoclopramide

Non-proprietary name Brand name	Non-proprietary name	Brand name (marketing authorization holder)
	a. Domperidone b. Metoclopramide hydrochloride c. Metoclopramide	a. Nauzelin Tablets 5, 10, Nauzelin OD Tablets 5, 10, Nauzelin Dry Syrup 1%, Nauzelin Suppository 10, 30, 60, and the others (Kyowa Kirin Co., Ltd., and the others) b. Primperan Injection 10mg, and the others (Nichi-Iko Pharmaceutical Co., Ltd., and the others) c. Primperan Tablets 5, Primperan Syrup 0.1%, Primperan Fine Granules 2%, and the others. (Nichi-Iko Pharmaceutical Co., Ltd., and the others)
Japanese market launch	See Attachment	
Indications	See Attachment	
Summary of revisions	1. A cautionary statement regarding serious arrhythmia should be added to the 8. IMPORTANT PRECAUTIONS section. 2. "Serious arrhythmia" should be added to the 11.1 Clinically Significant Adverse Reactions section in 11. ADVERSE REACTIONS.	
Investigation results and background of the revision	Based on the result of the National Database of Health Insurance Claims (NDB) study on the risk of serious arrhythmias associated with domperidone and metoclopramide (appendix), the PMDA determined that an increased risk of serious arrhythmias was suggested with both domperidone and metoclopramide. As a result of consultation with expert advisors regarding the appropriateness of the PMDA's views described above and the necessity of taking safety measures, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.	

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).

Attachment

Domperidone

No.	Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications
a.	Domperidone	Nauzelin Tablets 5, 10	Kyowa Kirin Co., Ltd.	September 1982	The following diseases and gastrointestinal symptoms (nausea, vomiting, inappetence, abdominal distension, upper abdominal discomfort, abdominal pain, heartburn eructation) Adults: Chronic gastritis, gastroparesis, post gastrectomy syndrome When antineoplastic agents or levodopa preparations are administered Children: Cyclic vomiting syndrome, upper respiratory tract When antineoplastic agents are administered
		Nauzelin OD Tablets 5, 10		December 2011	
		Nauzelin Dry Syrup 1%		September 1982	The following diseases and gastrointestinal symptoms (nausea, vomiting, inappetence, abdominal distension, abdominal pain) Children: Cyclic vomiting syndrome, pediatric diarrhoea, upper respiratory infection When antineoplastic agents are administered
		Nauzelin Suppository 10, 30, 60		September 1982	<Suppository 60 mg> Adults: The following diseases and gastrointestinal symptoms (nausea, vomiting, inappetence, abdominal distension, upper abdominal discomfort, heartburn) After gastric and duodenal

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

					surgery When antineoplastic agents are administered <Suppository 10 and 30 mg> Children: The following diseases and gastrointestinal symptoms (nausea, vomiting, inappetence, abdominal distension, abdominal pain) Cyclic vomiting syndrome, pediatric diarrhoea, upper respiratory infection When antineoplastic agents are administered
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Metoclopramide hydrochloride/metoclopramide

	Non-proprietary name	Brand name	Marketing authorization holder	Japanese market launch	Indications
b.	Metoclopramide hydrochloride	Primperan Injection 10mg	Nichi-Iko Pharmaceutical Co., Ltd.	October 1965	Gastrointestinal dysfunction (nausea, vomiting, inappetence, abdominal distension) in the
c.	Metoclopramide	Primperan Tablets 5	Nichi-Iko Pharmaceutical Co., Ltd.	October 1965	following cases
		Primperan Syrup 0.1%	Nichi-Iko Pharmaceutical Co., Ltd.	October 1965	Gastritis, gastric/duodenal ulcer, gallbladder/biliary tract disease, nephritis, uraemia, pediatric vomiting, administration of drug
		Primperan Fine Granules 2%	Nichi-Iko Pharmaceutical Co., Ltd.	May 1967	(antineoplastic agents, antibiotics, antituberculosis agents, anesthetics), gastric/endotracheal intubation, irradiation therapy, and post-laparotomy. Facilitation of barium passage during X-ray examination