

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

Pmda No. 51 Revised November 2024

(Based on previously reported cases, we have made revisions such as adding "Examples of drug products with the same active ingredient but different indications, dosage and administration, etc." In addition, examples of ingenuity and preventive measures are described on page 4.)

Mix-ups of Drugs Due to Name Similarities (No. 1) – Similarities of Nonproprietary Names –

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This is a joint project with the Project to Collect and Analyze Pharmaceutical Near-Miss Event Information by Japan Council for Quality Health Care. Please also refer to "Pharmaceutical Near-Miss Event Information to Be Shared No. 11 of Project to Collect and Analyze Pharmaceutical Near-Miss Event Information (11 2024)."

1 Drugs with Similar Nonproprietary Names

(Case 1) When a pharmacy received a prescription for "[nonproprietary] isosorbide mononitrate tablets 20 mg," the pharmacist misread the drug name and considered the prescription to be for "isosorbide dinitrate tablets 20 mg" and dispensed FRANDOL Tablets (isosorbide dinitrate: Therapeutic drug for ischemic heart disease) instead of ITOROL Tablets (isosorbide mononitrate: Therapeutic drug for angina pectoris) that should have been dispensed.

POINT Key points for safe use

- Be aware that some drugs have similar nonproprietary names, and be sure to check each drug name.
- Share information and raise awareness about drugs with similar nonproprietary names in your institution.

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処方せん

Isosorbide mononitrate 20mg
One tablet twice a day, morning and evening, after meals, for ● days

Let's see, "isosorbide dinitrate"...

Wait a second! Doesn't the prescription say "isosorbide mononitrate"?

[Nonproprietary] isosorbide mononitrate tablets 20 mg

Isosorbide mononitrate 20mg

Isosorbide dinitrate 20mg

Therapeutic drug for angina pectoris

Therapeutic drug for ischemic heart disease

Dispensing errors due to preconceptions

Examples of Similar Nonproprietary Names

(* “–” represents no original drug is available)

Nonproprietary names	Brand names*	Therapeutic category, etc.
Atenolol	TENORMIN	Cardioselective β -blockers
Arotinolol hydrochloride	–	Therapeutic drug for hypertension, angina pectoris, arrhythmia, and therapeutic drug for essential tremor
Atomoxetine hydrochloride	Strattera	Therapeutic drug for attention deficit hyperactivity disorder (selective noradrenaline reuptake inhibitor)
Amoxicillin hydrate	Sawacillin	Synthetic penicillin drug product
Isosorbide mononitrate	Itorol	ISMN therapeutic drug for angina pectoris
Isosorbide dinitrate	Frاندol, Nitorol	Therapeutic drugs for ischemic heart disease
Eszopiclone	Lunesta	Hypnotics
Estazolam	EURODIN	Hypnotics
Estazolam	EURODIN	Hypnotics
Etizolam	DEPAS	Anxiolytic
Ezetimibe	Zetia	Small intestine cholesterol transporter inhibitor (therapeutic drug for hyperlipidaemia)
Etizolam	DEPAS	Anxiolytic
Carbazochrome sodium sulfonate hydrate	ADONA	Hemostatic agent
Procarbazine hydrochloride	–	Antineoplastic agent
Clotiazepam	RIZE	Anxiolytic
Clonazepam	RIVOTRIL, Landsen	Antiepileptic drug
Clotiazepam	RIZE	Anxiolytic
Clopidogrel sulfate	Plavix	Antiplatelet agent
Chlorpromazine hydrochloride	CONTOMIN	Neuropsychiatric tranquilizer
Chlormadinone acetate	PROSTAL	Therapeutic drug for prostatic hypertrophy/cancer
Miglitol	SEIBULE	Diabetes mellitus postprandial hyperglycemia improving agent
Mitiglinide calcium hydrate	GLUFAST	Rapid-acting insulin secretagogue
Mirtazapine	REFLEX, REMERON	Noradrenaline/serotonergic antidepressants
Milnacipran hydrochloride	Toledomin	Serotonin noradrenaline reuptake inhibitor (SNRI)
Repaglinide	SUREPOST	Rapid-acting insulin secretagogue
Rebamipide	Mucosta	Therapeutic drug for gastritis/gastric ulcer

The information in the tables on this page and the next page is current as of MM 202X.

For more details, please refer to the latest package insert for each product available from the link below or the QR code on the right
<https://www.pmda.go.jp/PmdaSearch/iyakuSearch/> (only in Japanese)



2 Drugs you should be aware of having the same active ingredient but for different indications, etc.

- (Case 2)** “[Nonproprietary] salazosulfapyridine enteric coated tablets (antirheumatic drug)” were prescribed. An interview with the patient revealed that the patient had been diagnosed with ulcerative colitis, not rheumatoid arthritis. When the prescribing physician was questioned about this discrepancy, the drug was changed to “[Nonproprietary] salazosulfapyridine tablets (therapeutic drug for ulcerative colitis).”
- (Case 3)** On admission, the patient brought in “1 tablet of TRERIEF OD Tablets 25 mg (zonisamide: Therapeutic drug for Parkinson’s disease),” but Pharmacist A, who identified the drug, described “EXCEGRAN tablets 100 mg (antiepileptic drug)” with the same ingredient as a similar drug because TRERIEF OD Tablets was not in the hospital’s drug formulary. The doctor prescribed “EXCEGRAN Tablets,” but Pharmacist B noticed the error based on the difference in “indications” and corrected the prescription.

POINT Key points for safe use

- Some drugs have the same active ingredient with different indications, dosage and administration, etc.
- At the time of nonproprietary name prescription, considering or proposing alternative drugs, or dispensing, or auditing, confirm that prescription details are appropriate by referring to “4. Indications,” “6. Dosage and Administration,” etc., along with the “brand name” and “nonproprietary name” provided in the latest package insert.

Examples of drug products with the same active ingredient but different indications, dosage and administration, etc.

Active ingredient	Brand name (original drug), etc.	Indications, etc.
Salazosulfapyridine (tablets) (enteric coated tablets)	Salazopyrin tablets 500 mg	Ulcerative colitis, regional enteritis, nonspecific colitis
	Azulfidine EN tablets 250 mg/500 mg	Rheumatoid arthritis
Zonisamide	EXCEGRAN Tablets 100 mg/Powders 20%	Partial/generalized epilepsy (Note: For details, see the package insert.)
	TRERIEF OD Tablets 25 mg/50 mg	Parkinsonism associated with Parkinson’s disease and Lewy body dementia (Note: Indications vary by dose.)
Drospirenone/ ethinylestradiol	Yaz Flex combination tablets	Improvement of pain associated with endometriosis, dysmenorrhea, etc. (placebo tablets unavailable)
	Yaz combination tablets	Dysmenorrhea (placebo tablets available)
Metformin hydrochloride	(Generic product of METOGLUCO) Metformin hydrochloride tablets 250 mg MT “○○”	Type 2 diabetes mellitus Ovulation induction in and polycystic ovarian syndrome, etc. (Note: Maximum daily dose for adult patients with type 2 diabetes mellitus is 2,250 mg.)
	(Generic product of Glycoran) Metformin hydrochloride tablets 250 mg “○○”	Type 2 diabetes mellitus (Note: Maximum daily dose 750 mg)
Tadalafil	(Generic product of Zalutia) TADALAFIL tablets 2.5 mg/5 mg ZA “○○”	Urination disorder associated with prostatic hypertrophy
	(Generic product of Adcirca) TADALAFIL tablets 20 mg AD “○○”	Pulmonary arterial hypertension
	(Generic product of Cialis) TADALAFIL tablets 10 mg/20 mg CI “○○”	Erectile dysfunction

“○○” stands for a “trade name.”

Be aware that mix-ups are likely to occur at times, such as when a doctor prescribes a drug, when a pharmacist identifies a bring-in drug, or when switching from an original drug to a generic drug!



3 Examples of strategies and measures to prevent mix-ups due to similar names

PMDA Medical Safety Information No. 44 provides examples of strategies using the prescription ordering system.

<https://www.pmda.go.jp/files/000144997.pdf>

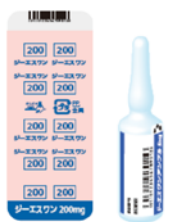


Provide the prescription with remarks indicating the name of the original drug and the name of a typical generic drug to prevent dispensing errors.*

* Even in this case, the premium for nonproprietary name prescriptions is available (see the Administrative Notice dated May 26, 2017, "Submission of Clarifications to Inquiries (No. 11)."

Use systems such as prescriptions with 2-dimensional symbols, such as QR codes, and electronic prescriptions, etc., to prevent prescription entry errors into the receipt computer.

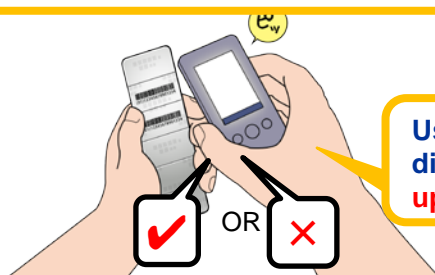
Dispensed package unit



(01)0498700000017



Use barcode authentication at dispensing/audit to prevent mix-ups.



Prevent mix-ups by skillfully using both the system and analog information, such as actual prescriptions, the medication record book, and patient information (disease name, laboratory results, etc.).

QR Code is a registered trademark of DENSO WAVE INCORPORATED.

The Japan Council for Quality Health Care issued information related to this "PMDA Medical Safety Information No. 51 Revised." Please refer to "Pharmaceutical Near-Miss Event Information to Be Shared No. 11 of Project to Collect and Analyze Pharmaceutical Near-Miss Event Information (11 2024)."

https://www.yakkyoku-hiyari.icqhc.or.jp/pdf/sharing_case_2024_11.pdf

About this information

- PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices.
- We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
- This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals. Access to the most up-to-date safety information is provided via the PMDA Medi-navi service.
- 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.

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