

# Medical Safety Information

Pharmaceuticals and Medical Devices Agency

**pmda** No. 51 September 2017

## Mix-up of Drugs Due to Similarity of Nonproprietary Names

### POINT Key points for safe use

**(Case)** When an insurance pharmacy received a nonproprietary name prescription for “isosorbide mononitrate tablets 20 mg”, the pharmacist misread the drug name and considered the prescription for “isosorbide dinitrate tablets 20 mg”, and dispensed FRANDOL Tablets instead of ITOROL Tablets that should have been dispensed.

### 1 Drugs with similar nonproprietary names

- Pharmacists need to understand that some drugs have similar nonproprietary names and exercise particular caution when dispensing them.

処方せん	
(この処方せんは、この保険薬局でも有効です。)	
公費負担番号	保険者番号
公費負担医療の受給者番号	被保険者証・被保険者手帳の記号・番号
氏名	保険医療機関の所在地及び名称
生年月日	電話番号
区分	保険医氏名
被保険者	郵送付番号
被扶養者	点数番号
交付年月日	処方せんの発行期間
平成 年 月 日	平成 年 月 日
処方	特記事項のある場合を除き、交付の日を含む7日以内の保険薬局に限り有効とする。
変更不可	個々の処方箋について、後発医薬品（ジェネリック医薬品）への変更は差し支えがあると判断した場合には、「変更不可」欄に「レ」又は「×」を記載し、「保険医署名」欄に署名又は記名・押印すること。
【般】一硝酸イソソルビド錠20mg 1日2錠 1回1錠 1日2回 朝夕食後 ○日分	
保険医署名	（「処方」欄に「レ」又は「×」を記載した場合は、署名又は記名・押印すること。）
備考	保険薬局が調剤時に機差を確認した場合の対応（特に特記事項のある場合は「レ」又は「×」を記載すること。） <input type="checkbox"/> 保険医療機関へ機差提供 <input type="checkbox"/> 保険医療機関へ機差提供
調剤年月日	公費負担番号
平成 年 月 日	
保険薬局の所在地及び名称	公費負担医療の受給者番号
調剤年月日	

**[Nonproprietary] Isosorbide mononitrate tablets 20 mg**



Isosorbide **mononitrate**  
 (一硝酸イソソルビド)

Isosorbide **dinitrate**  
 (硝酸イソソルビド)



## List of mix-up incidents in nonproprietary name prescription

Nonproprietary name	Brand name (original drug)
Isosorbide mononitrate(一硝酸イソソルビド) Isosorbide dinitrate(硝酸イソソルビド)	Itorol Frandol
Arotinolol hydrochloride (アロチノロール塩酸塩) Atenolol (アテノロール)	Arotinolol hydrochloride [DSP] Tenormin
Estazolam (エスタゾラム) Etizolam (エチゾラム)	Eurodin Depas
Cefcapene pivoxil hydrochloride (セフカペンピボキシル塩酸塩) Cefditoren pivoxil (セフジトレンピボキシル) Cefdinir (セフジニル) Cefpodoxime proxetil (セフポドキシムプロキセチル)	Flomox Meiact Cefzon Banan
Nicergoline (ニセルゴリン) Nicorandil (ニコランジル)	Sermion Sigmat
Nisoldipine (ニソルジピン) Nilvadipine (ニルバジピン)	Baymycard Nivadil
Fluvastatin (フルバスタチン) Pravastatin sodium (プラバスタチンNa)	Lochol Mevalotin
Clobetasol propionate (クロベタゾールプロピオン酸エステル) Clobetasone butyrate (クロベタゾン酪酸エステル)	Dermovate Kindavate
Betamethasone dipropionate (ベタメタゾンジプロピオン酸エステル) Betamethasone butyrate propionate (ベタメタゾン酪酸プロピオン酸エステル)	Rinderon-DP Antebate
Ranitidine (ラニチジン) Lafutidine (ラフチジン)	Zantac Protecadin
Ethyl loflazepate (ロフラゼパ酸エチル) Lorazepam (ロラゼパム)	Meilax Wypax

Nonproprietary name (nonproprietary prescription master name)	Brand name (original drug)
Salazosulfapyridine <b>Tablets</b> Salazosulfapyridine <b>Enteric-coated Tablets</b>	Salazopyrin Azulfidine EN
Theophylline Sustained-release Tablets <b>(12-hour to 24-hour duration)</b> Theophylline Sustained-release Tablets <b>(24-hour duration)</b>	Theodur Uniphyl LA, Unicon
Nifedipine Sustained-release Tablets <b>(12-hour duration)</b> Nifedipine Sustained-release Tablets <b>(24-hour duration)</b>	Adalat L Adalat CR



There have been many other kinds of drug mix-up incidents.  
 Let's avoid dispensing errors by learning and sharing the nonproprietary drug names that are often confused.

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Preventive measures against drug mix-up in nonproprietary name prescription

Example of prescription writing (1)

Example of prescription writing (2)

Prescription	No substitutions <input type="checkbox"/> If substitution with a generic drug is deemed inappropriate for an individual prescribed drug, place a check mark or X in the "No substitutions" column and sign in the "Name of insurance Doctor" blank or print your name and affix your seal.
	Rp1 [Nonproprietary] Isosorbide mononitrate tablets 20 mg, 2 tablets a day, 1 tablet at a time, twice a day, after breakfast and dinner; ___-day supply  (Remark: Brand name drug "ITOROL" or a generic product)
Remarks	Name of insurance Doctor (Place a check mark or X in the "No substitutions" column and sign or print your name and affix your seal.)

Prescription	No substitutions <input type="checkbox"/> If substitution with a generic drug is deemed inappropriate for an individual prescribed drug, place a check mark or X in the "No substitutions" column and sign or affix your seal in the "Name of insurance Doctor" blank.
	Rp1 [Nonproprietary] Isosorbide mononitrate tablets 20 mg, 2 tablets a day, 1 tablet at a time, twice a day, after breakfast and dinner; ___-day supply
Remarks	Name of insurance Doctor (Place a check mark or X in the "No substitutions" column and sign or print your name and affix your seal.)  Rp1: Brand name drug "ITOROL" or a generic product

In the Prescription column for each nonproprietary name prescription, write the original drug name or the typical generic product as a remark.

In the Remarks column, write the original drug name or the typical generic product.

A brand name or a typical generic product can be added for reference **if the nonproprietary name is such that there is particular concern over the risk of a mix-up.**

Even in this case, the premium for nonproprietary name prescriptions is available. However, since the product name shown together with the nonproprietary name is reference information on the prescribed drug, it is necessary to take measures to avoid the misunderstanding that it is to specify dispensing of a particular product. Please cooperate with the prescribing medical institution to prevent dispensing errors.



**The Ministry of Health, Labour and Welfare (MHLW) issued administrative notices related to PMDA Medical Safety Information No. 51.**

- Administrative Notice by the General Affairs Division, Health Policy Bureau; General Affairs Division, Pharmaceutical Safety and Environmental Health Bureau; and Safety Division, Pharmaceutical Safety and Environmental Health Bureau, dated May 26, 2017  
Summary of results of "Research on the Penetration of Standardized Prescription Format of Oral Drugs" funded by Health and Labour Sciences Research Grants Fiscal year (FY) 2015 (Research Project for Development of Community Medicine Infrastructures) (provision of information)
- Administrative Notice by the Medical Economics Division, Health Insurance Bureau, dated May 26, 2017  
"Submission of Clarifications to Inquiries (No. 11)"

**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 available via PMDA medi-navi.**

