This is the English version of the package insert of this product, translated from the Japanese package insert. The English version is provided for consumers who have purchased and use this product in Japan to help their understanding of its details. Please carefully read and fully understand the information given on this package insert before taking this product.

Cold remedy (Non-pyrine)

Pylon PL Granules

Product name: Pylon PL Granules

Class 2 OTC drug



Pylon PL Granules are a non-pyrine cold medicine that has an excellent effect on various cold symptoms such as "sore throat," "fever," and "running nose" with the action of four active ingredients: Salicylamide and Acetaminophen, which are antipyretic and analgesic components; Promethazine methylenedisalicylate, which is an antihistamine component; and Anhydrous caffeine, which helps to suppress pain.



Precautions



the product

(If you do not follow these instructions, the current symptoms may worsen or adverse reactions/incidents are more likely to occur.)

- 1. This product should not be taken in the following persons.
 - (1) Patients who have had an allergic symptom to this drug or its ingredients
 - Patients who have experienced asthma from taking this drug or other cold remedies, or antipyretic analgesics (3) Children under 15 years old
- 2. This drug should not be taken together with the following drugs: Other cold medicines, antipyretics/analgesics, sedatives, expectorants, internal medicine, etc. containing antihistamines (internal medicine for rhinitis, medicine
- for motion sickness, medicine for allergies, etc.) 3. After taking this drug, do not drive a car or operate machinery (sleepiness
- 4. Do not drink alcohol before/after taking this drug.
- 5. Do not take this drug for a long time.



Consultation

- 1. The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before administration.
 - Patients undergoing medical treatment from a physician or dentist

 - Persons diagnosed as having the following: heart disease, liver disease,
- kidney disease, gastric/duodenal ulcer, glaucoma

 2. If the following symptoms are observed after taking this drug, these may be
- adverse reactions, so immediately discontinue the use of this drug, and show this document to your physician, pharmacist, or registered salesperson for a consultation.

Affected area	Symptom	Affected area	Symptom
Skin	Rash/redness, itching	Urinary system	Urination difficulty
Gastrointestinal system	Nausea and vomiting, loss of appetite	Other	Excessive temperature decrease
Neuropsychiatric	Dizziness		

The following serious symptoms may occur in rare cases. In such cases, immediately seek medical aid:

Name of symptom	Symptom		
Shock (anaphylaxis)	Symptoms, such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after take.		
Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, acute generalised exanthematous pustulosis	Hyperthermia, ocular hyperaemia, eye discharge, lip erosion, pain throat, widespread skin rash/redness, small pimples (small pustules) on reddened skin, general malaise, anorexia, etc. may persist or suddenly worsen.		
Drug-induced hypersensitivity syndrome	Widespread skin redness, systemic rash, fever, general malaise, swollen lymph nodes (in the neck, axilla, groin or such) may occur.		
Hepatic function failure	Symptoms, such as fever, itching, rash, jaundice (yellowing of skin and white of eyes), brown urine, general malaise, loss of appetite, etc. may occur.		
Kidney disorders	Symptoms, such as fever, rash, reduced urinary volume, general oedema, general malaise, arthralgia (painful joints), diarrhea, etc. may occur.		
Interstitial pneumonia	Shortness and/or difficulties of breath when go upstairs or overwork, sudden dry cough and/or fever and its continuance		
Asthma	Symptoms, such as wheezing or hissing when breathing, and difficult breathing, etc. may occur.		

Pregnant women or women suspected of being pregnant
Patients who have experienced allergic symptoms associated with drugs, etc.
Persons with the following symptoms: hyperthermia, urination difficulty

If these symptoms persist or worsen, discontinue the use of this If these symptoms persist or worsen, discontinue the use of this drug, and show this document to your physician, pharmacist, or registered salesperson for a consultation:

Dry mouth, drowsiness

When symptoms do not improve even after taking this drug 5 to 6 times, stop taking the drug and consult a physician, pharmacist or registered salesperson, being sure to take this document with you.



Indications

Relief of various symptoms of a common cold; sore throat, fever, running nose, stuffy nose, sneezing, chills (feeling cold due to fever), headache, joint pain, and muscle pain.



Dosage and administration

Take the following amount with water or lukewarm water within 30 minutes after each meal.

Age	Single dose	Daily dosing frequency
Adults (15 years old and over)	1 sachet	3 times a day
Children under 15 years old	Not allow	ved to take this medicine

· Strictly follow the prescribed dosage and administration.



Ingredients and amounts

Pylon PL Granules are white granules, containing the following amounts of ingredients per 3 sachets (0.8 g \times 3 = the daily dose for adults):

Ingredient	Amount (per 3 sachets)	Mode of action	
Salicylamide	648 mg	To relieve pain and to reduce fever	
Acetaminophen	360 mg	To relieve pairi and to reduce lever	
Anhydrous caffeine	144 mg	To help relieve pain	
Promethazine methylenedisalicylate	32.4 mg	To relieve running nose, stuffy nose, and sneezing	

Additives include lactose hydrate, corn starch, sodium chloride, sucrose, and hydrated silicon dioxide



Precautions for storage and handling

- Store in a cool, low humidity place away from direct sunlight
- Keep out of reach of children.
- Do not transfer the medicine to a different container (It may lead to misuse or alter the quality of the drug.)
- Do not take the product after its expiration date





Contact information

For inquiries about this product, please contact the store where you purchased it or the following:

Shionogi Healthcare Co., Ltd. "Drug Information Center"

Tel: Osaka 06-6209-6948, Tokyo 03-3406-8450

Reception hours: 9:00-17:00 (excluding Saturdays, Sundays, and holidays)

For information on the "Relief System for Sufferers from Adverse

 Pharmaceuticals and Medical Devices Agency (PMDA) https://www.pmda.go.jp/kenkouhigai_camp/index.html

Tel: 0120-149-931 (toll-free number)

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