

**Make sure to read this instruction sheet before taking this medicine.
Additionally, store this sheet so that it can be referenced when needed.**

For severe throat pain, cough, runny nose and fever

PABRON ACE Pro-X TABLETS

Brand name: PABRON ACE Pro-X TABLETS

Class **2** OTC drug <Cold medicine>

◆ PABRON ACE Pro-X TABLETS is a cold medicine containing a combination of 7 active ingredients including ibuprofen, L-carbocisteine, ambroxol hydrochloride and pseudoephedrine hydrochloride. It is effective against 11 symptoms of severe cold, such as sore throat, cough, runny nose and fever.



Precautions for Use



Things You Must Not Do



(Failure to follow these precautions may lead to your current symptoms worsening or a greater chance of side effects or accidents occurring)

1 The following persons should not take this medicine:

- (1) Persons who have had allergic symptoms to this medicine or any of its ingredients.
- (2) Persons who have experienced asthma while taking this medicine or other cold medicines or antipyretic analgesics.
- (3) Children under 15 years of age.
- (4) Pregnant women whose due date is within 12 weeks.
- (5) Persons being treated or receiving medication for the following at a medical facility:
Gastric/duodenal ulcer, blood disease, liver disease, kidney disease, heart disease, hypertension, current treatment with zidovudine (Retrovir, etc.)
- (6) Persons with the following symptoms:
Difficulty urinating due to enlarged prostate

(7) Persons who have received any of the following diagnoses:

Hypertension, heart disease, thyroid dysfunction, diabetes

2 Do not use any of the following medicines while taking this medicine:

Other cold medicines, antipyretic analgesics, sedatives, antitussive expectorants, oral medicines containing antihistamines, etc. (oral medicines for rhinitis, motion sickness medicines, allergy medicines, etc.)

3 Do not drive a vehicle or operate machinery after taking this medicine

(You may experience drowsiness, etc.)

4 Do not take this drug if you are breastfeeding, or avoid breastfeeding if you are taking this drug

(This medicine has been confirmed to have transference into breast milk in animal tests)

5 Do not drink alcohol before or after taking this medicine

6 Do not take this medicine for more than 5 days



Things To Consult On

1 The following individuals should consult with their doctor, pharmacist, or a registered seller before taking this medicine

- (1) Persons receiving treatment from a doctor or dentist.
- (2) Persons who are pregnant or who think they may be pregnant.
- (3) Elderly persons.
- (4) Persons who have had allergic symptoms due to medication or similar substances in the past.
- (5) Persons who have experienced insomnia, dizziness, weakness, tremors or palpitations while taking cold medicines, antitussive expectorants, oral medicines for rhinitis, etc.
- (6) Persons with the following symptoms:
High fever, difficulty urinating
- (7) Persons who have been diagnosed with or had the following diseases:
Gastric/duodenal ulcer, blood disease, liver disease, kidney disease, bronchial asthma, systemic lupus erythematosus, mixed connective tissue disease, ulcerative colitis, Crohn's disease, glaucoma, respiratory dysfunction, obstructive sleep apnea, obesity
- (8) Persons receiving treatment with monoamine oxidase inhibitors (selegiline hydrochloride, etc.). (Selegiline hydrochloride is used for treatment of Parkinson's disease)

2 If any of the following symptoms appear after you have taken this medicine, you may be experiencing side effects. As such, discontinue use immediately and consult with your doctor, pharmacist or registered seller, bringing this instruction sheet with you

In rare cases, the following serious symptoms may occur.

In such cases, see a doctor immediately.

Symptom Name	Symptoms
Shock (anaphylaxis)	Itching, hives, hoarse voice, sneezing, itchy throat, breathlessness, palpitations, and confusion immediately after taking this medicine.
Blood disorder	Easy bruising, sudden high fever, chills, sore throat, bleeding tendencies (gum bleeding, nosebleed, etc.) and bleeding that does not stop easily.
Digestive system disorder	Black stool, vomiting of blood, bloody stool, blood and mucus in the stool (loose stool containing blood, mucus or pus), etc.
Mucocutaneous ocular syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, acute generalized exanthematous pustulosis	High fever, bloodshot eyes, eye discharge, lip sores, sore throat, widespread skin rash/redness, small bumps (small pustules) appearing on reddened skin, whole body sluggishness, loss of appetite, etc., that persists or worsens rapidly.
Liver dysfunction	Fever, itching, rash, jaundice (yellowing of the skin and whites of the eyes), brown urine, general sluggishness, loss of appetite, etc.
Kidney damage	Fever, rash, decreased urine output, general swelling, general sluggishness, joint pain, diarrhea, etc.
Aseptic meningitis	Severe headache accompanied by stiffness in the neck, fever, nausea/vomiting, etc. (Such symptoms are particularly frequently reported in those receiving treatment for systemic lupus erythematosus or mixed connective tissue disease.)
Myocardial infarction*	<u>Tightening of the chest, difficulty breathing and cold sweat.</u>
Cerebrovascular disorder*	<u>Sudden reduction or loss of consciousness, difficulty moving a hand or foot on one side, headache, vomiting, dizziness, difficulty speaking or forming words, etc.</u>
Interstitial pneumonia	Shortness of breath or difficulty breathing on exertion, such as when climbing stairs, dry cough and fever, etc. These symptoms may appear suddenly or persist.
Asthma	Difficulty breathing or a wheezing or whistling sound when breathing.
Aplastic anemia	Bruising, nosebleeds, bleeding gums, fever, pale skin and mucous membranes, fatigue, palpitations, shortness of breath, feeling unwell and dizzy, blood in urine, etc.


Relevant Area	Symptoms
Skin	Rash, redness, itching, edema, bruising
Digestive system	Nausea/vomiting, loss of appetite, stomach discomfort, stomach pain, canker sores, heartburn, upset stomach, gastrointestinal bleeding, abdominal pain, diarrhea, bloody stool, stomach/abdominal bloating
Neuropsychiatric system	Dizziness, numbness, insomnia, feeling depressed, nervousness, convulsion
Circulatory system	Palpitations
Respiratory system	Shortness of breath
Urinary tract	Difficulty urinating
Other	Blurred vision, ringing in ears, swelling, nosebleed, bleeding gums, bleeding that does not stop easily, bleeding, back pain, excessively low body temperature, feeling sluggish

Agranulocytosis	Sudden high fever, chills, sore throat, etc.
Respiratory depression	Shortness of breath, difficulty breathing, etc.

- The following symptoms may appear after taking this medicine. If these symptoms persist or worsen, discontinue use and consult with your doctor, pharmacist, or registered seller, bringing a copy of this instruction sheet with you
Constipation, dry mouth, drowsiness
- If symptoms do not improve after using this medicine 5 to 6 times, discontinue use and consult with your doctor, pharmacist or registered seller, bringing this instruction sheet with you (especially if fever lasts for more than 3 days or occurs repeatedly).

Usage/Dosage

Take the following dosages with room-temperature or lukewarm water within no more than 30 minutes after meals.

Age	Single dose	Number of doses
Adults (15 years and older)	3 tablets 	3 times a day
Under 15 years old	Do not take this medicine	

Note:

(1) Strictly follow the prescribed usage and dosage.

(2) How to take out the tablets:

As shown in the illustration, press the convex part of the PTP sheet containing the tablet hard with a fingertip to tear the aluminum foil on the reverse side, remove the tablet, and take it. (Accidental ingestion of the PTP sheet as-is may lead to unexpected accidents, such as penetration into the esophageal mucosa.)



Efficacy

Relieves cold symptoms (sore throat, cough, phlegm, runny nose, stuffy nose, sneezing, fever, chills (feeling cold due to fever), headache, joint pain, muscle pain)

For sore throat, fever, etc.



For cough/phlegm



For sneezing, runny nose, stuffy nose



Ingredients

In 3 tablets

Ibuprofen	200 mg	Works on the source of inflammation and pain to relieve sore throat and fever.
L-carbocisteine	250 mg	Returns airway mucus and mucous membranes toward their normal state and makes it easier to expel phlegm.
Ambroxol hydrochloride	15 mg	Activates the ciliary movement of the airway mucous membranes and smooths the surface of the mucous membranes, making it easier to discharge phlegm that causes throat symptoms.
Dihydrocodeine phosphate	8 mg	Acts on the cough center in the brain to relieve coughing.
Pseudoephedrine hydrochloride	45 mg	Vasoconstricting effect suppresses hyperemia/swelling of the mucous membranes of the nose and improves stuffy nose.
Chlorpheniramine maleate	2.5 mg	Suppresses symptoms of sneezing, runny nose and stuffy nose.
Riboflavin (vitamin B ₂)	4 mg	Replenishes vitamins consumed quickly during a cold.

Additives: Cellulose, anhydrous silicic acid, magnesium aluminometasilicate, sodium starch glycolate, hypromellose, calcium hydrogen phosphate, hydroxypropyl cellulose, magnesium stearate, talc

Note: Do not worry if your urine is yellow after taking the product. This is caused by vitamin B₂ contained in the product.

Precautions for Storage and Handling

- Store in a cool, dry place away from direct sunlight.
- Keep out of reach of children.
- Do not replace the medicine into a different container. (This may result in misuse or a change in quality)
- Do not take the product after the expiration date. Use this medicine within 6 months of opening, even if still within the expiration date. (In order to ensure quality)



Disclaimer on Multilingual OTC Product Information

- This product is a pharmaceutical product approved under a Japanese law, the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices, with a view to its sale and use in Japan.
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