

# Sustained-Release Pabron Tablets

- ◆ Sustained-Release Pabron Tablets contain 6 active ingredients including the antipyretic analgesic ibuprofen, ambroxol hydrochloride for airway mucosa care, and is effective against 11 severe symptoms associated with the common cold, such as sore throat, cough, runny nose, and fever.
- ◆ The "delayed action" of these tablets, consisting of a rapidly dissolving layer and a slowly dissolving layer, sustain the effect with just a twice daily dosing in the morning and evening.
- ◆ This common cold medicine is in small, easy-to-take tablets and do not contain caffeine.

## Indication

To alleviate cold symptoms (sore throat, cough, sputum, runny nose, stuffy nose, sneezing, fever, chill (chill due to fever), headache, joint pain, muscle pain)

## Dosage and administration

Take the following dose with cold or lukewarm water.

Take the drug within 30 minutes after breakfast and dinner whenever possible

Adults (15 years or over): 3 tablets per dose, 2 times daily

Under 15 years: Do not take

### Precaution

- Comply with the prescribed dosage and administration instructions.
- Do not split, crush, or grind tablets, but swallow them without chewing.

### How to take out the tablets

Press the convex part of the PTP sheet containing the tablet firmly with your fingertips, break the aluminum foil on the back side, and take out the tablets. (If the tablets are inadvertently taken together with the PTP sheet containing them, it will lead to unexpected accidents, such as the sharp edge sticking into the esophageal mucosa)

## Ingredient

In daily dose (6 tablets)

Ibuprofen 400mg

*d*-Chlorpheniramine Maleate 3.5mg

Dihydrocodeine Phosphate 16mg

*dl*-Methylephedrine Hydrochloride 60mg

Ambroxol hydrochloride 45mg

Riboflavin (vitamin B<sub>2</sub>) 8mg

### Excipients

Cellulose, anhydrous silicic acid, calcium hydrogen phosphate, hypromellose, sodium starch glycolate, magnesium stearate, citric acid

### Precaution

No need to worry if you have yellow urine after taking the drug because it is caused by the vitamin B<sub>2</sub> contained in the drug.

## Precautions

### When not to use the product

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

- This product should not be taken in the following persons
  - 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, antipyretic analgesics.
  - Children under 15 years old.
  - Pregnant women who are expected to give birth within 12 weeks.
- This drug should not be taken together with the following drugs
  - Other cold medicines, antipyretics/analgesics, sedatives, expectorants, and internal medicines, etc. containing antihistamines (internal medicine for rhinitis, medicine for motion sickness, medicine for allergies, etc.)
- After taking this drug, do not drive a car or operate machinery

(symptoms such as sleepiness may occur)

- For those who are lactating, do not use this medicine or avoid lactating while using this medicine
- Do not drink alcohol before and after taking this drug
- Do not take this medicine for more than 5 days

## Consultation

- 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.

Pregnant women or women suspected of being pregnant.

The elderly.

Patients who have experienced allergic symptoms associated with drugs, etc.

Persons with the following symptoms.

Hyperthermia, urination difficulty

Persons diagnosed as having the following.

Thyroid disease, diabetes, heart disease, hypertension, liver disease, kidney disease, glaucoma, systemic lupus erythematosus, mixed connective tissue disease, respiratory functional disorder, obstructive sleep apnea syndrome, and adiposity

Patients who experienced any of the following diseases.

Gastric/duodenal ulcer, ulcerative colitis, crohn's disease

- 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

Skin: rash/redness, itching, edema, and bruises

Gastrointestinal system: nausea/vomiting, loss of appetite, gastric discomfort, stomach pain, stomatitis, heartburn, heaviness in the stomach, gastrointestinal bleeding, abdominal pain, diarrhea, and bloody stool, feeling of stomach/abdominal distention

Neuropsychiatric system: dizziness, numbness

Cardiovascular system: palpitations

Respiratory system: shortness of breath

Urinary system: urination difficulty

Other: blurred vision, tinnitus, oedema, nosebleeds, bleeding from the gums, defects in hemostasis, bleeding, back pain, excessive drop of body temperature, and general malaise

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

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.

Oculomuocutaneous syndrome (stevens-johnson syndrome), toxic epidermal necrolysis: hyperthermia, ocular hyperaemia, eye discharge, lip erosion, pain throat, widespread skin rash/redness, etc. may persist or suddenly worsen.

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) and diarrhea, etc. may occur.

Aseptic meningitis: symptoms, such as severe headache with a tight sensation along the neck, fever and feeling nausea/vomiting, etc. may occur. (these symptoms are frequently reported particularly in patients under treatment for systemic lupus erythematosus or mixed connective tissue disease. )

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.

Aplastic anemia: symptoms, such as bruises, nose bleeds, bleeding gums, fever, pale appearance of skin and mucosa, fatigue, palpitations, shortness of breath, becoming dizzy from feeling sick and blood in the urine, etc. may occur.

Agranulocytosis: symptoms, such as acute high fever, chills and sore throat, etc. may occur.

Respiratory depression: shortness of breath, breathing difficulties, etc. may occur.

- The following symptoms may be observed after taking this drug. 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

Constipation, dry mouth, drowsiness

- When symptoms do not improve even after taking the medicine 3 to 4 times, stop taking this medicine and consult a physician, pharmacist, or registered salesperson, being sure to take this instruction leaflet with you (In particular, fever lasting for at least 3 days or repeating fever)

### Precautions for storage and handling

- Avoid direct sunlight, and store the product in a cool place with little humidity.
- Store the product beyond the reach of children.
- Do not transfer the drug to other containers. (It may lead to misuse or quality deterioration)
- Do not use the product past the expiration date. Even before the expiration date, use the product within 6 months after it is opened (to assure the quality).

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- 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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