

Please read the instructions carefully before using.

エスタック® EX ネオ

つらい「のどの痛み・鼻水・熱・せき」に 第②類医薬品

※ この医薬品は「使用上の注意」をよく読んでお使いください。

アレルギー体質の方は、必ず薬剤師、登録販売者にご相談ください。



S.TAC EX NEO

Designated Class 2 OTC drug

Cold medicine

Highly effective for severe “sore throat, runny nose, fever, and cough”

<Product Features>

- Highly effective for a severe cold. S.TAC® EX NEO is a cold medicine that combines 600 mg (daily dose) of ibuprofen, the largest amount in S.TAC history
- In addition, it uses our own technology to rapidly dissolve and promote fast absorption of ibuprofen.
- S.TAC® EX NEO contains ibuprofen that relieves sore throat and has a fever-lowering effect. It also contains isopropamide iodide and chlorpheniramine maleate which are highly effective for nasal symptoms. Ambroxol hydrochloride promotes the discharge of phlegm that is the cause of cough and relieves cough with dihydrocodeine phosphate.
- It comes in the PTP package that is convenient and easy to carry.

CAUTIONS FOR USE

CONTRAINDICATIONS

(Failure to observe the following may cause the present symptoms to worsen or produce adverse drug reactions and/or accidents.)

1. The following people must not take this drug:

- (1) Those with a previous allergic reaction to this drug or ingredients of the drug
- (2) Those who have ever suffered from asthma after taking this drug or other drugs for cold remedies or for relief of pain and fever
- (3) Children under 15 years of age
- (4) Pregnant women whose due date is within 12 weeks
- (5) Those who are receiving treatment or medication for the following diseases at medical institutions: Gastric and duodenal ulcers, blood disease, liver disease, kidney disease, heart disease, hypertension or those who are receiving zidovudine (Retrovir®)

2. Do not take this drug in combination with any of the following drugs:

Other cold remedies, pain relievers/fever reducers, sedatives, cough and expectorant medicines, antihistamine-containing oral drugs (e.g. oral nasal inflammation drugs, motion sickness drugs, anti-allergy drugs, hypnotics and sedatives, etc.) or gastrointestinal pain relievers and antispasmodics

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3. **Do not drive or operate machinery after taking this drug.**
(Sleepiness, blurred vision or excessive sensitivity to light may occur.)
4. **Breastfeeding women should not take this drug. If unavoidable, refrain from breastfeeding while taking this drug.**
5. **Do not drink alcohol before or after taking this drug.**
6. **Do not exceed 5 days of usage.**

WHEN to consult a doctor

1. The following people should consult a doctor, pharmacist or registered salesperson before taking this drug:

- (1) Those who are under the treatment of a doctor or dentist
- (2) Pregnant women or those who may become pregnant
- (3) Elderly people
- (4) Those with any previous allergic reactions to drugs or other things
- (5) Those with any of the following symptoms: High fever or urination difficulties
- (6) Those who were diagnosed with any of the following diseases:
Disrupted thyroid function, diabetes, heart disease, hypertension, liver disease, kidney disease, glaucoma, systemic lupus erythematosus, mixed connective-tissue disease, respiratory functional disorder, obstructive sleep apnoea syndrome (OSAS) or obesity
- (7) Those who have suffered from any of the following diseases: Gastric and duodenal ulcers, ulcerative colitis, Crohn's disease, blood disease, liver disease or kidney disease

2. The following symptoms may be adverse drug reactions. If any of these symptoms occur, STOP TAKING the drug immediately and consult a doctor, pharmacist or registered salesperson. Show them this leaflet.

Related areas	Symptoms
Skin	Rash, redness, itching or purpura
Digestive system	Nausea, vomiting, loss of appetite, stomach discomfort, stomachache, oral ulcer, heartburn, heavy stomach feeling, gastrointestinal bleeding, abdominal pains, diarrhea or stomach and abdominal fullness
Central nervous system	Dizziness/ vertigo, insomnia, moodiness or headache
Circulatory system	Palpitations
Respiratory system	Breath shortness
Urinary system	Urination difficulties
Other	Blurred vision, ringing in the ears, swelling, numbness, nose bleeding, gum bleeding, uncontrolled bleeding, bleeding, back pain, excessive fall in temperature, malaise, hot flushes on face or excessive sensitivity to light

In rare cases, the following serious symptoms could occur. In such an event, immediately consult a doctor.

Symptom's name	Symptoms
Shock (Anaphylaxis)	Itching of skin, hives, hoarseness, sneezing, itching of throat, tightness in the chest, palpitations, consciousness clouding, etc. which develop soon after taking the drug
Mucocutaneous ocular syndrome (Stevens-Johnson syndrome), Toxic Epidermal necrolysis	Persistent or acute worsening of high fever, bloodshot eyes, eye discharge, lip erosion, sore throat, widespread rash, redness, etc.
Liver dysfunction	Fever, itching, rash, jaundice (skin and whites of the eyes turn yellow), brown urine, general malaise, loss of appetite, etc.
Kidney disorder	Fever, rash, reduction of urine output, generalized swelling, general malaise, joint pain, diarrhea, etc.
Aseptic meningitis	Severe headache with neck muscle rigidity, fever, nausea, vomiting, etc. (These symptoms are mainly reported in patients undergoing treatment for systemic lupus erythematosus or mixed connective-tissue disease.)
Interstitial pneumonia	Shortness of breath, difficulty breathing when going up stairs or performing strenuous activity, dry cough, fever or other symptoms, which happen suddenly or continuously
Asthma	Wheezing or crowing sound when breathing breathlessness, etc.
Blood disorder	Throat pain, fever, general malaise, whitish face and inside of the eyelid, bleeding easily (gum bleeding, nose bleeding, etc.), and purpura (color does not disappear even if pressed) may occur.
Digestive disorder	Black stools, hematemesis, bloody stools, and mucous and bloody stools (soft stools with blood, mucus, and pus), etc. may occur.
Respiratory depression	Shortness of breath or difficulty breathing, etc.

3. You may develop the following symptoms after taking this drug. If the symptoms continue or worsen, stop taking the drug and consult a doctor, pharmacist or registered salesperson. Show them this leaflet.
Constipation, dry mouth or sleepiness
4. If the symptoms do not improve after 5 or 6 doses (especially, when fever lasts 3 days or more, or recurs), stop taking the drug and consult a doctor, pharmacist or registered salesperson. Show them this leaflet.

Indications

Alleviation of various common cold symptoms (sore throat, fever, runny nose, nasal congestion, cough, sputum, sneezing, chills, headache, joint pain and muscle pain)

Dosage and Directions

Take the following dose 3 times a day, preferably within 30 minutes of a meal. This drug should be taken with either cold or lukewarm water.

Age	Adult (15 years or over)	Under 15 years
One dose	2 tablets	Do not take

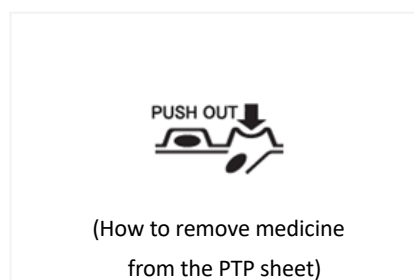
<Cautions regarding dosage and directions>

(1) Strictly observe the dosage and directions.

(2) <How to remove the tablet>

As shown in the right figure, with the fingertip strongly push the convex portion of the PTP sheet containing a tablet, break the aluminum foil on the back side and take it out.

(Swallowing a tablet without removing the PTP sheet by mistake may cause unexpected problems such as the PTP sheet sticking to the esophageal mucous membrane.)



Ingredients

Six tablets contain (daily dose):

- Ibuprofen - 600 mg
- Isopropamide iodide - 6 mg
- Chlorpheniramine maleate - 7.5 mg
- Ambroxol hydrochloride - 45 mg
- Dihydrocodeine phosphate - 24 mg
- dl-Methylephedrine hydrochloride - 60 mg
- Magnesium oxide - 300 mg
- Anhydrous caffeine - 75 mg

Additives

Anhydrous silicic acid, cellulose, lactose, hydroxypropyl cellulose, hypromellose, crospovidone, macrogol, D-mannitol, magnesium stearate, talc, titanium oxide, corn starch, polyvinyl alcohol-acrylic acid-methyl methacrylate copolymer

Storage and Handling Cautions

- (1) Store this drug in a cool, dry place away from sunlight and moisture.
- (2) Keep out of reach of children.
- (3) Do not transfer this drug to a different container as it may cause misuse or deterioration.
- (4) Do not take this drug after the expiration date.

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The marketing of this drug has been approved for domestic sales in accordance with the Japanese Pharmaceutical and Medical Devices Act (PMD Act.)