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This document serves as reference information. Please ensure to read the information provided with the product.

Underlined parts: Revisions made in October 2024

[Keep this information leaflet with this medication and be sure to read it before taking the medication.]

Brand name: S. TAC EX NEO

S. TAC® EX NEO

Class ② OTC drug

[Common Cold Medication] for distressing symptoms of "sore throat, nasal discharge, fever, and cough"

<Product Features>

- For distressing common cold symptoms. S. TAC EX NEO contains ibuprofen 600 mg (equivalent to the daily dose) which is the maximum dose amount in the history of the S. TAC brand products.
- In addition, the unique technology, which allows ibuprofen to dissolve quickly and accelerates ibuprofen absorption, was adopted for this medication.
- Ibuprofen relieves sore throat and exhibits antipyretic activity. This medication contains isopropamide iodide and chlorpheniramine maleate which are effective against nasal symptoms. Dihydrocodeine phosphate promotes expectoration of sputum, which causes cough, and cough is suppressed by dihydrocodeine phosphate in combination with ambroxol hydrochloride.
- The press-through package (PTP) is convenient for carrying.



Precautions for Use



Contraindications

If you do not follow the precautions exactly as listed below, your current symptoms may worsen and you may be placed at increased risk of side effects or the risk of having some accidents.

- The following persons must not take this medication:**
 - Persons who have had an allergic reaction to any of the ingredients of S. TAC EX NEO.
 - Persons who have experienced asthma after taking this medication or after taking other common cold medications or antipyretic-analgesics.
 - Children under 15 years of age.
 - Pregnant women whose due date is within 12 weeks ahead.
 - Persons who are receiving any treatment for any of the following diseases or receiving the following drug, at a medical institution: Gastroduodenal ulcers, blood diseases, liver diseases, kidney diseases, heart diseases, hypertension, and persons receiving zidovudine (Retrovir)
- Do not take any of the following medications during the period of taking S. TAC EX NEO:**
Other common cold medications, antipyretic-analgesics, sedatives, antitussive-expectorant medications, oral medications containing antihistamines (e.g., oral rhinitis medications, motion sickness medications, anti-allergic medications, hypnotic sedatives), gastrointestinal analgesic-antispasmodic medications
- Do not operate vehicles or machinery after taking this medication.**
(Symptoms such as sleepiness, blurred vision, abnormal brightness may occur.)
- Breast-feeding women are advised not to take S. TAC EX NEO or to stop breast-feeding if this medication is to be taken.**
- This medication must not be taken soon before or soon after alcohol intake.**
- Do not take this medication for more than 5 consecutive days.**



Consultation

- The following persons should consult a physician, pharmacist, or registered salesperson before taking this medication:**
 - Persons who are receiving any treatment from a physician or dentist.
 - Women who are or may be pregnant.
 - Elderly persons.
 - Persons who have had any allergic reactions to drugs or other substances.
 - Persons with the following symptoms: Hyperthermia (high fever), dysuria
 - Persons who have received a diagnosis of any of the following diseases: Thyroid dysfunction, diabetes mellitus, glaucoma, systemic lupus erythematosus, mixed connective tissue disease, bronchial asthma, respiratory dysfunction, obstructive sleep apnea syndrome, obesity
 - Persons who have had any of the following diseases: Gastroduodenal ulcers, ulcerative colitis, Crohn's disease, blood diseases, liver diseases, kidney diseases
- If any of the symptoms listed below develop after taking S. TAC EX NEO, they might be side effects of the medication. Stop taking this medication immediately and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.**

Affected area	Symptoms
Skin	Rash/redness, swelling, itching
Gastrointestinal	Nausea/vomiting, inappetence, stomach discomfort, stomachache, stomatitis, heartburn, heavy feeling in the stomach, gastrointestinal hemorrhage, abdominal pain, diarrhea, stomach fullness/bloating
Neuropsychiatric	Dizziness, sleeplessness, feeling depressed, headache
Cardiovascular	Palpitations
Respiratory	Shortness of breath
Urinary	Dysuria
Other	Blurred vision, tinnitus, swelling, numbness, back pain, excessively decreased body temperature, facial hot flushes, abnormal brightness

In rare cases, any of the serious symptoms listed below may occur. In such cases, immediately consult a physician.

Name of symptoms	Symptoms
Shock (anaphylaxis)	Itchy skin, urticaria, hoarse voice, sneezing, itchy throat, respiratory distress, palpitations, clouding of consciousness or such occurring immediately after taking this medication.
Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis	Symptoms, such as high fever, ocular hyperemia, eye discharge, sore lips, sore throat, rashes and redness over an extensive area of the skin, persisting or suddenly worsening.

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(Continued on the reverse side)

(Continued from the front side)

Name of symptoms	Symptoms
Hepatic impairment	Fever, itching, rash, jaundice (yellowing of the skin and whites of the eyes), brown urine, general malaise, inappetence or such occurring.
Renal disorders	Fever, rashes, decreased urine output, generalized swelling, general malaise, arthralgia (pain in joints), diarrhea or such occurring.
Aseptic meningitis	Symptoms such as severe headache with neck stiffness, fever, and nausea/vomiting occurring. (Frequent occurrences of such symptoms have been reported particularly among patients who are undergoing treatment for systemic lupus erythematosus or mixed connective tissue disease.)
Myocardial infarction	Pain with chest tightness, respiratory distress, and cold sweat occurring.
Cerebrovascular disorders	The following symptoms suddenly occurring: Decreased or loss of consciousness, difficulty in moving hand and foot unilaterally, headache, vomiting, dizziness, difficulty speaking, and speech impairment.
Interstitial pneumonia	The following symptoms suddenly occurring or persisting: Shortness of breath or respiratory distress when climbing stairs or slightly overworking, dry cough, and fever.
Asthma	Breathing sounds, such as wheezing and whistling, respiratory distress and such occurring.
Blood disorders	The following symptoms occurring: Sore throat, fever, general malaise, face pallor or pallor of the inner surface of the eyelid, bleeding tendencies (e.g., gingival bleeding, nasal bleeding), and bruising (discoloration does not disappear even after pressing on the skin).
Gastrointestinal disorders	The following symptoms occurring: Black stools, hematemesis, bloody stools, and mucous bloody stools (soft feces with blood, mucous and pus).
Respiratory depression	Shortness of breath, respiratory distress and such.

- Any of the conditions mentioned below may occur after taking S. TAC EX NEO. If such symptoms persist or worsen, stop taking this medication and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.

Constipation, thirst, sleepiness

- If there is no alleviation of common cold symptoms after taking 5 or 6 doses (particularly if fever persists for 3 or more days or recurs), stop taking this medication and consult a physician, pharmacist, or registered salesperson, presenting this leaflet.

Indications

Alleviation of common cold symptoms (sore throat, fever, nasal discharge, nasal stuffiness, cough, sputum, sneezing, chills, headache, joint pain, and muscle pain)

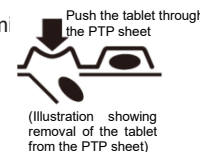
Dosage and Administration

Take a dose of S. TAC EX NEO, according to the table below, with cold or lukewarm water, 3 times daily. Each dose should be taken within 30 minutes after a meal whenever possible.

Age	Adults (aged 15 years or older)	Children under 15 years of age
Dose	2 tablets	× This medication must not be taken.

<Precautions concerning Dosage and Administration>

- (1) S. TAC EX NEO must be used strictly in accordance with the specified dosage and administration.
- (2) How to remove the tablet: As shown in the illustration on the right, firmly press the raised portion of the press-through package (PTP) with a fingertip to push the tablet through the aluminum foil on the reverse side. (If the PTP sheet is mistakenly swallowed, its sharp edges may perforate the esophageal mucosa or lead to incidental events.)



Ingredients

in a total of 6 tablets (the 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

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

Precautions for Storage and Handling

- (1) Store in a dry, cool place away from direct sunlight.
- (2) Keep out of the reach of children.
- (3) Do not transfer the contents to another container (which may lead to drug misuse or changes in the quality of this product).
- (4) Do not take this medication after the expiration date.

Contact Information

Inquiries should be made to the drugstore where you purchased the product or to the customer service office.

Customer Service Office, SSP Co., Ltd. Phone: 0120-028-193

Opening hours: 9:00 to 17:30 (closed on Saturdays, Sundays, and Japanese public holidays)

Manufactured and Distributed by:



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