

Please read the instructions carefully before using.

# エスタックイブ®

かぜの諸症状（のどの痛み・熱）の緩和に **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 IBU

Designated Class 2 OTC drug

Cold medicine

<Product Features>

S.TAC IBU® is a general cold medicine containing ibuprofen that relieves fever and sore throat.

It relieves cold symptoms such as sore throat, chills, fever and runny nose.

### 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

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

Other cold medicines, 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.)

**3. Do not drive or operate machinery after taking this drug.**

(Sleepiness 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.**

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SSP Co., Ltd.

## 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 or Crohn's 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 bloody stool |
| Central nervous system | Dizziness/vertigo   |
| Circulatory system     | Palpitations  |
| Respiratory system     | Breath shortness  |
| Urinary system         | Urination difficulties  |
| Other                  | Blurred vision, ringing in the ears, swelling, nose bleeding, gum bleeding, uncontrolled bleeding, bleeding, back pain, excessive fall in temperature or malaise                        |

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.   |

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| Symptom's name         | Symptoms   |
|------------------------|--|
| 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.<br>(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 happens suddenly or continuously  |
| Asthma                 | Wheezing or crowing sound when breathing breathlessness, etc.  |
| Aplastic anemia        | Purpura, nose bleeding, gum bleeding, fever, pale skin, pale mucosa, tiredness, palpitations, breathlessness, giddy feeling accompanied by queasy feeling, bloody urine, etc.  |
| Agranulocytosis        | Sudden high fever, chill, sore throat, etc.  |
| 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, chills, runny nose, nasal congestion, sneezing, fever, headache, cough, sputum, 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 | 3 tablets                | Do not take    |

<Cautions regarding dosage and directions>

Strictly observe the dosage and directions.

## Ingredients

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Nine tablets contain (daily dose):

- Ibuprofen - 450 mg
- Dihydrocodeine phosphate - 24 mg
- dl-Methylephedrine hydrochloride - 60 mg
- Chlorpheniramine maleate - 7.5 mg
- Anhydrous caffeine - 75 mg
- Thiamine nitrate (vitamin B<sub>1</sub> nitrate) - 24 mg
- Ascorbic acid (vitamin C) - 300 mg

## Additives

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Anhydrous silicic acid, cellulose, lactose, white soft sugar, hydroxypropyl cellulose, hypromellose, macrogol, calcium carbonate, carnauba wax, magnesium stearate, talc, titanium oxide, partly pregelatinized starch, pullulan and polyoxyethylene polyoxypropylene glycol

## Storage and Handling Cautions

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- (1) Store this drug in a cool, dry place away from sunlight and moisture. Tighten the bottle cap securely.
- (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 touch tablets with wet hands as it may cause the coating to become uneven or discolored.
- (5) The stuffing is to protect tablets against damage during shipping. Please discard it after opening.
- (6) 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.)