

This document is an English summary of the package insert written in Japanese, and is provided only for convenience of the consumers who buy and use this product in Japan. Please make sure that you read this document and understand the information of the package insert before taking this product. Please keep the package insert so that you can show it to your doctor, dentist, pharmacist, or certified drug salesperson whenever you need.

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For menstrual pain, throat sore and headache

Designated Second-class OTC drugs

Non-pyrazolone antipyretic analgesic
(Containing ibuprofen)

SEDES CURE

 SHIONOGI & CO., LTD.

SEDES CURE shows potent analgesic effects on menstrual pain, throat sore, headache, etc. by a combination of ibuprofen with a potent antipyretic analgesic effect and allylisopropylacetylurea and anhydrous caffeine to increase its efficacy. SEDES CURE, a small tablet, can be easily swallowed and shows analgesic antipyretic effects.



PRECAUTIONS



Unusable cases

(If you do not follow precautions, your current symptoms may get worse, or some side effects and/or accidents may occur.)

- Do not take this product if you have any of the following histories.
 - A history of allergic symptoms caused by this product or any of the ingredients.
 - A history of asthma after taking this product, other antipyretic analgesics, or cold remedies.
 - A Child under 15 years old
 - A pregnant woman within 12 weeks of the estimated of delivery date
- Do not take the following medicines while taking this product:
Other antipyretic analgesics, cold remedies, tranquilizers, motion sickness drugs
- Do not operate vehicles or machinery after taking this product. This product may induce drowsiness.
- Do not drink alcohol before and after taking this product.
- Avoid long-term use of this product.



Cases to consult

- If you correspond to any of the following, ask your doctor, dentist, pharmacist, or certified drug salesperson:
 - A patient who is in treatment by a doctor or a dentist.
 - A pregnant woman, or a woman who may be pregnant.
 - A lactating mother
 - An elderly person.
 - A person with a history of allergic symptoms caused by drugs or others.
 - A patient with any of the following:
Heart disease, kidney disease, liver disease, systemic lupus erythematosus or mixed connective tissue disease
 - A history of any of the following:
Gastric and/or duodenal ulcer, ulcerative colitis or Crohn 's disease
- Stop taking this product right away when the symptoms described below occur after taking this product, and ask your doctor, pharmacist, or certified drug salesperson showing the package insert and this document. These symptoms may be caused by adverse reactions.

Involved sites	Symptoms
Skin	Rash and/or redness, itching, bruise
Digestive system	Nausea and/or vomiting, anorexia, stomachache, stomach discomfort, stomatitis, heartburn, stomach heavy feeling, gastrointestinal bleeding, abdominal pain, diarrhea, blood feces
Neuropsychiatric	Dizziness
Circulatory organ	Throb, panting
Others	Bleary eyes, ringing ears, edema, nose bleeding, gum bleeding, uncontrolled bleeding, bleeding, back pain, excessive body temperature decrease, physical lassitude

Serious symptoms described below may occur at low frequency. If they are observed, go see a doctor right away.

Name of symptoms	Symptoms
Shock (anaphylaxis)	Itching of skin, urticaria, hoarseness, sneezing, itching of throat, feeling of suffocation, palpitations, impaired consciousness, etc. may occur immediately after taking this product.
Oculomucocutaneous syndrome (Stevens-Johnson syndrome) Toxic epidermal necrolysis	Hyperpyrexia, ocular hyperemia, eye mucus, sore lips, sore throat, skin rash/redness in extensive skin, etc. may persist or suddenly get worse.
Hepatic dysfunction	Fever, itching, rash, jaundice (yellowing of skin and/or the white of eyes), dark urine, general sick feeling, loss of appetite, etc. may occur.
Renal disorders	Fever, rash, reduced urine output, generalized edema, general sick feeling, arthralgia (joint pain), diarrhea, etc. may occur.

(To be continued to the back page)

Name of symptoms	Symptoms
Aseptic meningitis	Symptoms such as intense headache with tension in the neck, fever, nausea and vomiting may appear. (These symptoms were commonly reported in patients under treatment especially for systemic lupus erythematosus or mixed connective tissue disease.)
Asthma	Noisy breathing, feeling of suffocation, etc. may occur.
Aplastic anemia	Bruising, nose bleeding, gum bleeding, fever, pale skin and/or mucous membrane, tired feeling, palpitation, breathlessness, dizzy turn with feeling sick, bloody urine, etc. may occur.
Agranulocytosis	Sudden fever, ague, sore throat, etc. may occur.

- The following symptom may occur after taking this product. If it persists or gets worse, stop taking this product and ask your doctor, pharmacist or certified drug salesperson, showing the package insert and this document.
Constipation, diarrhea, drowsiness
- If the symptom does not get better even after 5 to 6 doses of this product, stop taking this product and ask your doctor, dentist, pharmacist, or certified drug salesperson, showing the package insert and this document.

..... INDICATIONS

- Analgesic for headache, menstrual cramps (menstrual pain), toothache, low back pain, pain with shoulder stiffness, joint pain, nerve pain, posttraumatic pain, pain after tooth extraction, throat sore, earache, muscle ache, pain of bruises, pain of fractures, and pain of sprains.
- Antipyretic for chills and fevers.

..... DOSAGE AND ADMINISTRATION

Take this product at the following dosage with cool or warm water preferably after meals, at intervals of 4 hours or more.

Age	Dose	Number of doses a day
Adults (15 years or over)	2 tablets	3 doses or less
Children (under 15 years)		Not allowed

- Follow the specified dosage and administration strictly.
- How to take out a tablet from a press-through package (PTP) sheet:
As shown in the right figure, press the protruded portion of the PTP sheet with your finger to break the aluminum film and take out a tablet. (If the PTP sheet is swallowed, its sharp edges may perforate your esophagus, resulting in serious complications.)



..... INGREDIENTS/CONTENTS

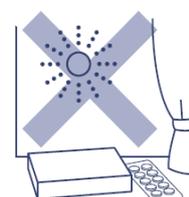
SEDES CURE is a white film-coated tablet. Each tablet contains the ingredients described below.

Ingredient	Content per tablet	Effects
Ibuprofen	75 mg	Fever reduction, pain relief
Allylisopropylacetylurea	30 mg	Increase of pain-relieving effect
Anhydrous caffeine	40 mg	Increase of pain-relieving effect, headache relief

The excipients include crystalline cellulose, corn starch, light anhydrous silicic acid, pregelatinized starch, low-substituted hydroxypropylcellulose, talc, magnesium stearate, hypromellose, macrogol 6000, titanium oxide and carnauba wax.

..... PRECAUTIONS FOR STRAGE AND HANDLING

- The product should be stored in a cool place protected from direct sunlight and at low humidity.
- Keep this product out of the reach of children.
- Do not transfer the tablets from the PTP sheet to another container (This may cause misuse or quality degradation of the product).
- Do not take any expired product.



..... REFERENCES SHOULD BE MADE

For inquiries or further information on this product, please contact the drug store where you purchased this product or the following.
"Drug Information Center"
SHIONOGI & CO., LTD.
Telephone: Osaka 06-6209-6948, Tokyo 03-3406-8450
Time: 9:00 to 17:00 (except Saturdays, Sundays, and national holidays)

Manufactured and Distributed by:
SHIONOGI & CO., LTD.
1-8, Doshomachi 3-chome, Chuo-ku,
Osaka 541-0045, Japan