

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.

3

For intolerable and considerable pain

Designated Second-class OTC drugs

Pyrazolone antipyretic analgesic

SEDES HIGH granule (SEDES HIGH G)

 SHIONOGI & CO., LTD.

SEDES HIGH granule (SEDES HIGH G) is highly effective against considerable pains due to the composition of 4 ingredients containing isopropylantipyrene with potent analgesic 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.
- 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.
 - 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, ulcer in stomach or duodenum.
- 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	Involved sites	Symptoms
Skin	Rash and/or redness, itching	Neuropsychiatric	Dizziness
Digestive system	Nausea and/or vomiting, anorexia	Others	Excessive body temperature decrease

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 Acute generalized exanthematous pustulosis	Hyperpyrexia, ocular hyperemia, eye mucus, sore lips, sore throat, skin rash/redness in extensive skin, small eruptions (pustules) on reddened skin, general sick feeling, loss of appetite, 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.
Interstitial pneumonia	Breath shortness and/or suffocation feeling may occur with walking up stairs or getting a little exercise. Dry cough, fever, etc. may suddenly appear or persist.
Asthma	Noisy breathing, feeling of suffocation, etc. may occur.

(To be continued to the back page)

3. 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.
Drowsiness
4. 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, nerve pain, low back pain, post-traumatic pain, pain after tooth extraction, throat sore, earache, joint pain, muscle ache, pain with shoulder stiffness, 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)	1 g of granule in a single strip package	3 doses or less
Children (under 15 years)	Not allowed	

- Follow the specified dosage and administration strictly.

..... **INGREDIENTS/CONTENTS**

SEDES HIGH G is a white granular medicine. One gram of the granule in a single strip package contains the ingredients described below.

Ingredient	Content per tablet	Effects
Isopropylantipyrine (IPA)	150 mg	Fever reduction, pain relief
Acetaminophen	250 mg	
Allylisopropylacetylurea	60 mg	Increase of pain-relieving effect
Anhydrous caffeine	50 mg	Increase of pain-relieving effect, headache relief

The excipients include lactose hydrate, hydroxypropylcellulose, methylcellulose, and hydrated silicon dioxide.

..... **PRECAUTIONS FOR STORAGE AND HANDLING**

- (1) The product should be stored in a cool place protected from direct sunlight and at low humidity.
- (2) Keep this product out of the reach of children.
- (3) Do not transfer the granule to another container (This may cause misuse or quality degradation of the product).
- (4) 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