(\_ underlined parts: revised in January 2023) It supports display and voice reading in multiple languages.

Product features
OR Translator.



Effective for unbearable and severe pain

Pyrine-based antipyretic analgesic

# SEDES HIGH





**Sedes High** contains four ingredients, including isopropylantipyrine, which has a strong analgesic effect, and has excellent analgesic effects even for severe pain. Small, easy-to-take tablets work quickly and have long-lasting effects.



Please read carefully



Precautions



When not to use the product

(If you do not follow these instructions, the current symptoms may worsen or adverse reactions/incidents are more likely to occur.)

- 1. This product should not be taken in the following persons.
  - (1) Patients who have had an allergic symptom to this drug or its ingredients
  - (2) Patients who have experienced asthma from taking this drug, or other antipyretic analgesics, or cold remedies
- 2. This drug should not be taken together with the following drugs:
  - Other antipyretics/analgesics, cold medicine, sedatives, medicine for motion sickness
- 3. After taking this drug, do not drive a car nor operate machinery (sleepiness may occur)
- 4. Do not drink alcohol before/after taking this drug.
- 5. Do not take this drug for a long time.



Consultation

- 1. The following persons should contact a physician, dentist, pharmacist, or registered salesperson for a consultation before administration.
- (1) Patients undergoing medical treatment from a physician or dentist.
- (2) Pregnant women or women suspected of being pregnant.
- (3) The elderly
- (4) Patients who have experienced allergic symptoms associated with drugs, etc.
- (5) Persons diagnosed as having the following: heart disease, kidney disease, liver disease, gastric/duodenal ulcer
- 2. If the following symptoms are observed after taking this drug, these may be adverse reactions, so immediately discontinue the use of this drug, and show this document to your physician, pharmacist, or registered salesperson for a consultation.

| Affected area   | Symptom               | Affected area           | Symptom                        |
|---|-----------------------|-------------------------|--------------------------------|
| Skin  | Rash/redness, itching | Neuropsychiatric system | Dizziness                      |
| Gastrointestinal system Nausea and vomiting, loss of appetite |                       | Other                   | Excessive temperature decrease |

The following serious symptoms may occur in rare cases. In such cases immediately seek medical aid:

| Name of symptom  | Symptom  |  |
|--|--|--|
| Shock<br>(anaphylaxis)   | Symptoms, such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after take.                                  |  |
| Oculomucocutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis, acute generalised exanthematous pustulosis | Hyperthermia, ocular hyperaemia, eye discharge, lip erosion, pain throat, widespread skin rash/redness, small pimples (small pustules) on reddened skin, general malaise, anorexia, etc. may persist or suddenly worsen. |  |
| Drug-induced hypersensitivity syndrome   | Widespread skin redness, systemic rash, fever, general malaise, swollen lymph nodes (in the neck, armpit, groin, etc.) may occur.  |  |
| Hepatic function failure   | Symptoms, such as fever, itching, rash, jaundice (yellowing of skin and white of eyes), brown urine, general malaise, loss of appetite, etc. may occur.  |  |
| Kidney disorders   | Symptoms, such as fever, rash, reduced urinary volume, general oedema, general malaise, arthralgia (painful joints), diarrhea, etc. may occur.   |  |
| Interstitial pneumonia   | Shortness and/or difficulties of breath when go upstairs or overwork, sudden dry cough and/or fever and its continuance  |  |
| Asthma   | Symptoms, such as wheezing or hissing when breathing, and difficult breathing, etc. may occur.   |  |

(continued on the reverse side)

- 3. The following symptom may be observed after taking this drug. If this symptom persists or worsens, discontinue the use of this drug, and show this document to your physician, pharmacist, or registered salesperson for a consultation: Drowsiness
- 4. When symptoms do not improve even after taking the medicine 5 to 6 times, stop taking this drug and consult a physician, dentist, pharmacist or registered salesperson, being sure to take this document instruction leaflet with you.



#### Indications

- O Relief of headache, painful menses (menstrual pain), toothache, neuralgia, lumbago, traumatic pain, pain after tooth extraction, sore throat (throat pain), earache, joint pain, muscular pain, pain due to stiff shoulders, contusion pain, bone fracture pain, and pain associated with sprain (sprain pain)
- O Relief of fever at the time of chills (feeling cold due to fever) and fever



#### Dosage and administration

Take the following amount with water or lukewarm water. If possible, avoid taking the medicine on an empty stomach. Take this medicine in intervals of at least 4 hours.

| Age                         | Single dose | Daily dosing frequency      |  |
|-----------------------------|-------------|-----------------------------|--|
| Adults (15 years and older) | 2 tablets   | Not more than 3 times a day |  |
| Children under 15 years old | Not allo    | wed to take this medicine   |  |

- Strictly follow the prescribed dosage and administration.
- How to take out the tablet

As shown in the right figure, press the raised part of the PTP sheet containing the tablet firmly with your fingertips to break the aluminum foil on the back, take out the tablet and swallow it. (If the PTP sheet is swallowed by mistake, it may lead to unexpected accidents such as piercing the esophageal mucosa.)

How to take out the tablet

Push it out with your finger



Take out the tablet and swallow it.



### Ingredient and amounts

Sedes High is a white, double-layered tablet, containing the following amounts of ingredients per 1 tablet:

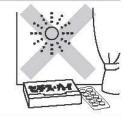
| Ingredients               | Contents | Function                                      |  |
|---------------------------|----------|---|--|
| Isopropylantipyrine (IPA) | 75 mg    | I o reduce fever and to relieve pain          |  |
| Acetaminophen             | 125 mg   |   |  |
| Allylisopropylacetylurea  | 30 mg    | To help relieve pain                          |  |
| Caffeine anhydrous        | 25 mg    | To help relieve pain and to relieve headaches |  |

**Additives** include carmellose calcium, croscarmellose sodium, povidone, magnesium stearate, crystalline cellulose, corn starch, lactose hydrate, and hydroxypropyl cellulose



## Precautions for storage and handling

- (1) Store in a cool, low humidity place away from direct sunlight.
- (2) Store out of reach of children.
- (3) Do not remove from the PTP sheet and transfer to another container. (This may lead to misuse or alter the quality of the drug.)
- (4) Do not take products after its expiration date.





### **Contact Information**

For inquiries about this product, please contact the store where you purchased it or the following:

● Shionogi Healthcare Co., Ltd. "Drug Information Center" Tel: Osaka 06-6209-6948, Tokyo 03-3406-8450 Reception hours: 9:00-17:00 (excluding Saturdays, Sundays, and holidays)

For information on the "Relief System for Sufferers from Adverse Drug Reactions"

● Pharmaceuticals and Medical Devices Agency (PMDA) https://www.pmda.go.jp/kenkouhigai\_camp/index.html Tel: 0120-149-931 (toll-free number)

Manufactured and Distributed by:

Shionogi Healthcare Co., Ltd.

2-6-18 Kitahama, Chuo-ku, Osaka