

This is the English version of the package insert of this product, translated from the Japanese package insert. The English version is provided for consumers who have purchased and use this product in Japan to help their understanding of its details. Please carefully read and fully understand the information given on this package insert before taking this product.

20 (underlined parts:
revised in January 2023)

It supports display and voice reading in multiple languages.

Product features
QR Translator.



Works quickly for headaches, fevers,
and menstrual pain

A non-pyrene antipyretic analgesic

Product name: New Sedes Tablets

Class 2 OTC drug

New Sedes Tablets



New Sedes Tablets contains four ingredients, which have a strong analgesic effect. It is a non-pyrene antipyretic analgesic that works quickly and is gentle on the stomach.



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.)

- 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
- This drug should not be taken together with the following drugs:**
Other antipyretics/analgesics, cold medicine, sedatives, medicine for motion sickness
- After taking this drug, do not drive a car nor operate machinery (sleepiness may occur)**
- Do not drink alcohol before/after taking this drug.**
- Do not take this drug for a long time.**



Consultation

- 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) Children (under 15 years old) who have chickenpox (varicella) or influenza, or are suspected thereof.
 - (4) The elderly
 - (5) Patients who have experienced allergic symptoms associated with drugs, etc.
 - (6) Persons diagnosed as having the following: heart disease, kidney disease, liver disease, gastric/duodenal ulcer.

- 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 (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.
<u>Drug-induced hypersensitivity syndrome</u>	<u>Widespread skin redness, systemic rash, fever, general malaise, swollen lymph nodes (in the neck, armpit, groin, etc.) may occur.</u>
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.

- 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
- 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.**

(continued on the reverse side)



Indications

- 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)
- 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 old and over)	2 tablets	Not more than 3 times a day
Children between 7 to 14 years old	1 tablet	
Infants/toddlers (under 7 years old)	Not allowed to take this medicine	

- Strictly follow the prescribed dosage and administration.
- When allowing children to take the medicine, a guardian must be present to watch and tell such them how take it.
- 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

New Sedes tablets are white tablets, containing the following amounts of ingredients per 1 tablet:

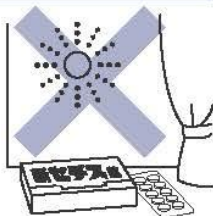
Ingredients	Contents	Function
Ethenzamide	200 mg	To reduce fever and to relieve pain
Acetaminophen	80 mg	
Allylisopropylacetylurea	30 mg	To help relieve pain
Caffeine anhydrous	40 mg	To help relieve pain and to relieve headaches

Additives include lactose hydrate, carmellose calcium, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate.



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 that have passed their 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)

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