

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 pain with shoulder stiffness, low back pain and headache

Designated Second-class OTC drugs

Non-pyrazolone antipyretic analgesic
(Containing vitamin B₁ derivative)

SEDES V

 SHIONOGI & CO., LTD.

SEDES V shows potent antipyretic analgesic effects due to the composition of ethenzamide, acetaminophen, etc. Furthermore, SEDES V contains an absorbable vitamin B₁ derivative (dicethiamine hydrochloride hydrate) for the purposes of increase of pain-relieving effect and supply of vitamin B₁ consumed during fevers. SEDES V, a non-pyrazolone antipyretic analgesic drug, acts fast for pain with shoulder stiffness, low back pain and headache and is gentle to the stomach.



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.
 - A child (under 15 years old) either definitely or possibly infected with varicella (chickenpox) or influenza.
 - 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, toothache, menstrual cramps (menstrual pain), pain with shoulder stiffness, nerve pain, low back pain, post-traumatic pain, pain after tooth extraction, throat sore, earache, joint pain, 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 (7 years or over, and under 15 years) | 1 tablet | |
| Children (under 7 years) | Not allowed | |

- Follow the specified dosage and administration strictly.
- Children should be administered this product under control of patients.
- 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**

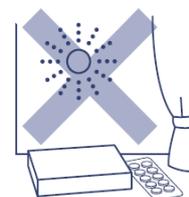
SEDES V is a white tablet. Each tablet contains the ingredients described below.

| Ingredient | Content per tablet | Effects |
|--|--------------------|---|
| Ethenzamide | 200 mg | Fever reduction, pain relief |
| Acetaminophen | 80 mg | |
| Allylisopropylacetylurea | 30 mg | Increase of pain-relieving effect |
| Anhydrous caffeine | 40 mg | Increase of pain-relieving effect, headache relief |
| Dicethiamine hydrochloride hydrate (Vitamin B ₁ derivative) | 4mg | Increase of pain-relieving effect, supply of vitamin B ₁ consumed during fevers. |

The excipients include carmellose calcium, crystalline cellulose, hydroxypropylcellulose, and magnesium stearate.

..... **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 tablets from the PTP sheet 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)

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