This information sheet must be read before use. Keep it in a safe place so that you can read it when necessary.

ロゼレムS®

A sleep-improving medicine for difficulty falling asleep

Guidance-Required Drugs

Characteristics

Our body has an internal clock that regulates the bodily rhythm on a cycle of approximately one day. Our sleep is closely related to this rhythm.

- When taken before bedtime, Rozerem S acts on the melatonin receptor* in the brain, adjusts the internal clock that plays the role of switching between sleep and wakefulness, and shifts the sleep-wake balance toward sleep, thereby inducing natural sleep.
  *Melatonin receptors have sleep-promoting effects (adjustment of sleep/wake balance).
- A small film-coated tablet, approximately 7 mm in diameter, is to be taken once daily.

⚠ Precautions for use

What you should not do

(If you do not follow the precautions listed below, your current symptoms may worsen, or you may be at an increased risk of adverse reactions and accidents.)

1. The following people should not take this drug:

(1) People who have developed allergic symptoms to this drug or any ingredient of this drug
(2) Children under 15 years of age
(3) Women who are or may be pregnant
(4) People who are being treated for the following diseases at medical institutions
Sleep disorders such as sleep apnea syndrome, psychiatric disorders associated with sleeplessness (depression, mania, schizophrenia, neurosis, dementia, etc.), liver disease
(5) People being treated with fluvoxamine maleate (Depromel, Luvox, etc.)

2. Do not use any of the following drugs while taking this drug:

Other sleep-improving drugs or hypnotics, cold medicines, antipyretic analgesics, antitussive and expectorant drugs, oral medicines containing antihistamines (oral medicines for rhinitis, motion sickness medicines, anti-allergic medicines, etc.)

3. Do not drive or operate machinery after taking this drug.

(Accidents may occur due to sleepiness, etc. If you continue to feel sleepy or experience lassitude on the day after taking this drug, do not drive or operate machinery until these symptoms disappear.)

4. Lactating women should not take this drug or should avoid breastfeeding if taking this drug.

5. Do not drink alcohol before and after taking this drug.

6. The drug should be used only when you have difficulty falling asleep.

7. Do not take this drug for more than 2 weeks (if you need to take this drug for more than 2 weeks, consult a physician or pharmacist).

Consultation

1. The following people should consult a physician or pharmacist before taking this drug:

(1) People under treatment by a physician
(2) Elderly people
(3) People with the following symptoms in addition to difficulty falling asleep
Severe daytime sleepiness, shallow sleep with waking in the middle of the night, depressed mood, pessimism, difficulty feeling tired or sleepy, easily excited, hallucination/auditory hallucination (hallucinatory voices), delusion, impaired memory, loss of the sense of time and place
(4) People with a history of any of the following conditions
Sleep disorders such as insomnia and sleep apnea syndrome, psychiatric disorders associated with sleeplessness (depression, mania, schizophrenia, neurosis, dementia, etc.)

2. Stop taking this drug immediately and consult a physician or pharmacist taking this leaflet with you if the following symptoms appear after taking this drug. These symptoms might be adverse reactions to the drug.

Related site	Symptoms
Skin	Rash/redness, itching
Digestive organ	Constipation, nausea
Neuropsychiatric system	Dizziness, headache, daytime sleepiness, nightmare
Other	Malaise

(Continued on the back)

The following serious symptoms may rarely occur. In such cases, immediately consult a physician.

Name of symptom	Symptoms
Shock (anaphylaxis)	Itchy skin, hives, hoarse voice, sneezing, itchy throat, sense of difficulty in breathing, palpitations, clouding of consciousness, etc. occur immediately after taking this drug.

3. **Stop taking this drug and consult a physician or pharmacist taking this leaflet with you if abnormalities in menstruation, menstrual irregularity, amenorrhea, lactation in men or women who are not in lactation period, decreased sexual desire, etc. are observed.**
4. **Stop taking this drug and consult a physician or pharmacist taking this leaflet with you if symptoms do not improve after taking this drug 2 to 3 times strictly following the specified dosage and administration (1 tablet once daily).**

Indications

Relief of the following symptom associated with temporary sleeplessness: difficulty falling asleep

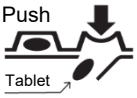
Dosage and administration

Take the following amount without chewing once daily, with cold or warm water within 30 minutes before bedtime.

Age	Dose	Daily dosing frequency
15 years or over	1 tablet	Once
Under 15 years	Do not take	

< Precautions related to dosage and administration >

(1) Follow the dosage and administration strictly.
(2) Do not take this drug except at bedtime.
(3) Do not take this drug with a meal or immediately after a meal (adequate effect may not be obtained).
(4) How to take out tablets
Before taking, remove the tablet from the packaging by firmly pressing the raised portion of the PTP sheet with a fingertip to push the tablet out through the aluminum foil on the back, as shown in the figure (if the PTP sheet is accidentally swallowed, it could pierce the mucous membrane of the esophagus, possibly causing an unforeseen accident).



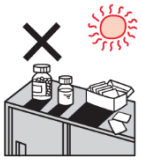
Ingredients

In 1 tablet (daily dose)

Ingredient	Content
Ramelteon	8 mg

Additives: Lactose hydrate, corn starch, hydroxypropylcellulose, magnesium stearate, hypromellose, copovidone, titanium oxide, ferric oxide, macrogol

Storage and Handling



(1) Store in the box in a dry, cool place away from direct sunlight.
(2) Keep out of the reach of children.
(3) To prevent improper use or loss of quality, do not transfer the product to another container.
(4) Do not use this product after the expiration date.
(5) Enter the date when the inner pouch (aluminum pouch) was opened in the space for "Date of opening" on the box.
(6) Once the inner pouch (aluminum pouch) is opened, take this drug within about 6 months to maintain quality.

CONTACT INFORMATION

For inquiries regarding this product, please contact the store where you purchased it or the contact information below.

Alinamin Pharmaceutical Co., Ltd. [Customer Consultation Desk]
Toll-free number: 0120-567-087
Reception hours: 9 a.m. to 5 p.m. (excluding Saturdays, Sundays, and public holidays)

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