Guidance-Required Drug

Sleep-improving drug

Rozerem® S

Pre-purchase Checklist for Proper Use

Before purchasing Rozerem® S, check the contents of this flow chart with a pharmacist to see if you can take this drug.
According to the pharmacist's judgment, it may be recommended that you visit a medical institution.

(1) You are under treatment by a physician or taking any prescription drugs (If not applicable, start with Section (2)).

[Check the items below.] *** If there are items about which you are unsure by yourself, consult a physician or pharmacist.**

☐ You are being treated for the following diseases:
Sleep disorder such as sleep apnea syndrome, restless legs syndrome, and periodic limb movement disorder, psychiatric disorder with sleeplessness (depression, mania, schizophrenia, neurosis, dementia, etc.), chronic obstructive pulmonary disease, liver disease

☐ You are taking the following drugs:
Fluvoxamine maleate (Depromel, Luvox, etc.): antidepressants

There are applicable items or items about which you are unsure. → You cannot take this drug. Consult a physician or pharmacist.

No applicable items ↓

☐ You are taking other sleep-improving drugs or hypnotics (including both prescription drugs and over-the-counter [OTC] drugs).

☐ You are under treatment by a physician.

☐ You are being treated with the following drugs:
- CYP1A2 inhibitors: quinolone antibiotics, etc.
- CYP2C9 inhibitors: fluconazole, etc.
- CYP3A4 inhibitors: macrolide antibiotics, ketoconazole, etc.
- CYP inducers: rifampicin, etc.

☐ Symptoms of sleeplessness appeared following the start of taking drugs such as anti-Parkinson drugs (levodopa, etc.), antihypertensive drugs (propranolol, etc.), and steroids (prednisolone, etc.).

There are applicable items or items about which you are unsure. → Since you may not be able to take this drug, consult a physician or pharmacist taking your medication record book with you.

No applicable items ↓

Proceed to (2) below.

After consultation, it has been confirmed that there is no issue. ←

(2) You are not under treatment by a physician nor taking any prescription drugs, or it has been confirmed that the items mentioned in Section (1) do not apply to you.

[Check the items below.]

☐ You are under 15 years of age.
☐ You have developed allergic symptoms to this drug or any ingredient of this drug.
☐ You are or may be pregnant.

There are applicable items. → You cannot take this drug. Consult a physician or pharmacist.

No applicable items ↓

☐ You are going to re-purchase the product within a short period of time (the previous purchase date: MM DD, YYYY).
☐ You are an elderly person.
☐ You have 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, difficult to feel tired or sleepy, easily excited, hallucination/auditory hallucination (hallucinatory voices), delusion, impaired memory, loss of the sense of time and place
☐ You have a history of any of the following diseases:
Sleep disorder such as insomnia, sleep apnea syndrome, restless legs syndrome, and periodic limb movement disorder, psychiatric disorder with sleeplessness (depression, mania, schizophrenia, neurosis, dementia, etc.), chronic obstructive pulmonary disease

There are applicable items. → Consult a physician or pharmacist.

No applicable items ↓

After consultation, it has been confirmed that there is no issue. ↓

Before taking this product, receive instructions from a pharmacist and carefully read the package insert and the information provided for users. Take the product exactly as directed (1 tablet once daily).

This drug must be taken according to the followings:

- The drug should be used only when you have difficulty falling asleep as a symptom of temporary sleeplessness.
- 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.
- Stop taking this drug and consult a physician or pharmacist in the following cases:
  - Abnormalities in menstruation, menstrual irregularity, amenorrhea, lactation in men or women who are not in lactation period, decreased sexual desire, etc. are observed.
  - Symptoms do not improve after taking this drug 2 to 3 times strictly following the specified dosage and administration (1 tablet once daily).

Consult a pharmacist if you have any questions about purchasing or taking the product.