Information Sheet for the Proper Selection and Purchase of Medicines

Guidance-Required Drugs	Be sure to read the package insert before use.

1	Name	Rozerem S
2	Ingredients/ contents	Ramelteon 8 mg per tablet (daily dose)
3	Dosage and administration	For those aged 15 years or older, take 1 tablet without chewing once daily, with cold or warm water within 30 minutes before bedtime.
4	Indications	Relief of the following symptom associated with temporary sleeplessness: difficulty falling asleep
5	Matters necessary to prevent health hazards	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 antihistamine (oral medicines for rhinitis, motion sickness medicines, anti-allergic medicines, etc.) 3. Do not drive or operate machinery after taking this drug. 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). Please consult a pharmacist before use if any of the following applies to you: • People under treatment by a physician, elderly people • 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 • 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.)
6	Items judged necessary by pharmacists	

[Precautions]

1. This sheet provides information to help customers select and purchase medicines appropriately.
2. According to laws and regulations, information shall be provided for all Guidance-Required Drugs and for Class 1 drugs unless the pharmacist judges such provision unnecessary.
3. If there are any changes, etc. in your physical condition after using this drug (adverse reactions, etc.), please discontinue the use and immediately consult a pharmacist at the store where you purchased the drug.

[2026.5]