

Patient Information Sheet: Zaleplon (marketed as Sonata)

This is a summary of the most important information about Sonata provided by the FDA.

What is Sonata used for?

Sonata is used to treat short-term difficulty in falling asleep. Sonata has been shown to decrease the time to sleep onset for up to 30 days in clinical studies. Sonata has not been shown to increase your total sleep time or decrease the number of times you wake up after falling asleep.

In general, medications used to bring on sleep should only be used for 7- 10 days.

Who Should Not Take Sonata?

Do not take Sonata if you are allergic to Sonata or any of its ingredients. Sonata contains FD&C Yellow No. 5 dye (tartrazine) that may cause allergic reactions in certain people such as asthma-like symptoms and difficulty breathing. Patients who are allergic to aspirin may be more likely to have a reaction to Sonata.

General Precautions with Sonata:

Sonata, like all sleep medicines, may make you drowsy during the day. The amount of drowsiness you feel depends upon how your body reacts to Sonata and the dose of Sonata you are taking. If you experience drowsiness during the day, talk to your doctor.

If your sleep problems do not get better or you begin to have unusual thinking or behavior changes while you take Sonata, they may be due to another medical reason. Tell your doctor right away.

If you abruptly stop taking Sonata you may experience withdrawal symptoms.

You may have more trouble falling asleep the first few nights after you stop taking Sonata than before starting Sonata, (rebound insomnia). This problem usually goes away on its own after 1-2 nights.

Withdrawal symptoms may occur when sleep medicines are stopped suddenly after being used daily for a long time. In some cases, withdrawal symptoms may include unpleasant feelings. In severe cases, stomach and muscle cramps, vomiting, sweating, shakiness, and rarely seizures may occur. These more severe withdrawal symptoms are very uncommon. Although withdrawal symptoms have not been observed in studies of Sonata so far, there is, nevertheless, the risk of such events in association with the use of any sleep medicines.

You may experience a certain type of memory loss (amnesia). This can usually be avoided by taking Sonata only when you are able to get 4 or more hours of sleep before you need to be active again. If you have memory problems when taking Sonata, tell your doctor.

There is a risk of becoming dependent on Sonata, as with any sleeping medication. If you have a history of addiction to alcohol or drugs your risk of your becoming dependent is higher. Be sure to tell your doctor about previous addictions to alcohol or drugs before taking Sonata.

Until you know if Sonata causes you drowsiness during the day, be extremely careful while doing anything that requires your complete attention, or physical coordination, like driving a car, or operating machinery.

Never drink alcohol while you are taking Sonata or any other sleep medication. Alcohol can increase the side effects of Sonata

What Should I Tell My Healthcare Professional?

Tell your doctor if you or your family notice any changes in your thinking or any new behaviors. Some people using sleep medications have experienced:

- More outgoing or aggressive behavior than normal
- Change in personality
- Confusion
- Strange behavior
- Agitation
- Hallucinations
- Worsening of depression
- Suicidal thoughts

Because certain other medications can interact with Sonata, review all medications that you are taking with your doctor, or healthcare provider, including those you take without a prescription.

Tell your doctor if you have or have had a history of liver problems. Your doctor will evaluate and decide Sonata is right for you.

What are some possible side effects of Sonata? In addition to the items noted above:

- Drowsiness
- Dizziness
- Lightheadedness
- Difficulty with coordination
- Amnesia (memory loss)
- Headache
- Nausea
- Excessive sleepiness
- Abdominal Pain
- Eye Pain
- Tremors
- Falls (especially in the elderly)