

Sonata[®] is a registered trademark of King Pharmaceuticals Research and Development, Inc.

STORAGE CONDITIONS

Store at controlled room temperature, 20°C to 25°C (68°F to 77°F).

Dispense in a light-resistant container as defined in the USP.

Prescribing Information as of December 2007.

Distributed by: King Pharmaceuticals, Inc., Bristol, TN 37620

Manufactured by: Corepharma LLC, 215 Wood Avenue Middlesex, NJ 08846

LAB-0615-1.0

Revision: April 2013

MEDICATION GUIDE

SONATA[®] (Suh NAH tah) CAPSULES

C-IV

(Zaleplon CAPSULES)

Read this Medication Guide before you start taking SONATA and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment. You and your doctor should talk about SONATA when you start taking it and at regular checkups.

What is the most important information I should know about SONATA?

After taking SONATA, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with SONATA. Reported activities include:

- driving a car (“sleep-driving”)
- making and eating food
- talking on the phone
- having sex
- sleep-walking

Important:

1. Take SONATA exactly as prescribed

- Do not take more SONATA than prescribed.
- Take SONATA right before you get in bed, not sooner.

2. Do not take SONATA if you:

- drink alcohol
- take other medicines that can make you sleepy. Talk to your doctor about all of your medicines. Your doctor will tell you if you can take SONATA with your other medicines
- cannot get a full night’s sleep

3. Call your doctor right away if you find out that you have done any of the above activities after taking SONATA.

What is SONATA?

SONATA is a sedative-hypnotic (sleep) medicine. SONATA is used in adults for the short-term treatment of the symptom of trouble falling asleep from insomnia. SONATA does not treat other symptoms of insomnia which include waking up too early in the morning and waking up often during the night.

SONATA is not for children.

SONATA is a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep SONATA in a safe place to prevent misuse and abuse. Selling or giving away SONATA may harm others, and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take SONATA?

Do not take SONATA if you are allergic to anything in it. See the end of this Medication Guide for a complete list of ingredients in SONATA.

SONATA may not be right for you. Before starting SONATA, tell your doctor about all of your health conditions, including if you:

- have a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- have kidney or liver disease
- have a lung disease or breathing problems
- are pregnant, planning to become pregnant, or breastfeeding

Tell your doctor about all of the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Medicines can interact, sometimes causing side effects. **Do not take SONATA with other medicines that can make you sleepy.**

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I take SONATA?

- **Take SONATA exactly as prescribed.** Do not take more SONATA than prescribed for you.
- **Take SONATA right before you get into bed.** Or you can take SONATA after you have been in bed and have trouble falling asleep.
- Do not take SONATA with or right after a meal.
- **Do not take SONATA unless you are able to get a full night's sleep before you must be active again.**
- **Call your healthcare provider if your insomnia worsens or is not better within 7 to 10 days.** This may mean that there is another condition causing your sleep problem.
- If you take too much SONATA or overdose, call your doctor or poison control center right away, or get emergency treatment.

What are the possible side effects of SONATA?

Serious side effects of SONATA include:

- **getting out of bed while not being fully awake and do an activity that you do not know you are doing.** (See “What is the most important information I should know about SONATA?”)
- **abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.
- **memory loss**
- **anxiety**
- **severe allergic reactions.** Symptoms include swelling of the tongue or throat, trouble breathing, and nausea and vomiting. Get emergency medical help if you get these symptoms after taking SONATA.

Call your doctor right away if you have any of the above side effects or any other side effects that worry you while using SONATA.

Common side effects of SONATA include:

- drowsiness
- lightheadedness
- dizziness
- “pins and needles” feeling on your skin
- difficulty with coordination
- You may still feel drowsy the next day after taking SONATA. **Do not drive or do other dangerous activities after taking SONATA until you feel fully awake.**
- You may have withdrawal symptoms when you stop taking SONATA. Withdrawal symptoms include unpleasant feelings, stomach and muscle cramps, vomiting, sweating, shakiness, and rarely seizures. You may also have more trouble sleeping the first few nights after Sonata is stopped. The problem usually goes away on its own after 1 or 2 nights.

These are not all the side effects of SONATA. Ask your doctor or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SONATA?

- Store SONATA at room temperature between 68° and 77° F (20° to 25°C).
- Protect from light.
- **Keep SONATA and all medicines out of the reach of children.**

General Information about SONATA

- Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide.
- Do not use SONATA for a condition for which it was not prescribed.
- Do not give SONATA to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about SONATA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about SONATA that was written for healthcare professionals.

If you would like more information, contact the King Pharmaceuticals, Inc. Professional Information Services at 1-800-776-3637.

What are the ingredients in SONATA?

Active Ingredient: zaleplon

Inactive Ingredients: microcrystalline cellulose, pregelatinized starch, silicon dioxide, sodium lauryl sulfate, magnesium stearate, lactose, gelatin, titanium dioxide, D&C yellow #10, FD&C blue #1, FD&C green #3, and FD&C yellow #5.

• **Sonata 5 mg** – A hard gelatin capsule with an opaque green cap and an opaque pale green body. “5 mg” in black ink is printed on the cap and “SONATA” in black ink is printed on the body.

• **Sonata 10 mg** – A hard gelatin capsule with an opaque green cap and an opaque light green body. “10 mg” in black ink is printed on the cap and “SONATA” in black ink is printed on the body.

Rx only

SONATA is distributed by:

King Pharmaceuticals, Inc.

Bristol, Tennessee 37620

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

M110078/ Rev. August 2011

LAB-0616-1.0