

APPENDIX B

Example of the Food and Drug Administration Atypical Antipsychotic Drug Patient Information Sheet



Patient Information Sheet

[Generic drug name]
(marketed as [brand name])

This is a summary of the most important information about [drug name]. For details, talk to your healthcare professional.

What Is [drug name]?

- [Drug name] is in a class of medications called atypical antipsychotics. Antipsychotic medicines are used to treat symptoms of schizophrenia that may include hearing voices, seeing things, or sensing things that are not there, mistaken beliefs or unusual suspiciousness.
- [Drug name] is used to treat mixed or manic episodes in adults who have a condition called Bipolar I disorder. Bipolar disorder is a mental illness that causes extreme mood swings.

What Are The Risks?

The following are the risks and potential side effects of [drug name] therapy. However, this list is not complete.

- **Increased chance of death in elderly persons.** Elderly patients treated with atypical antipsychotics, such as [drug name], for dementia had a higher chance for death than patients who did not take the medicine. [Drug name] is not approved for dementia.
- **A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).** NMS can cause a high fever, stiff muscles, sweating a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- **A movement problem called tardive dyskinesia (TD).** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- **High blood sugar and diabetes.** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- **Strokes** have happened in older patients treated for mental illness from dementia. [Drug name] is not approved for this use.
- **Other serious side effects** with [drug name] may include low blood pressure seen as dizziness, increased heart beat and

possibly fainting, seizures, increased body temperature, and difficulty swallowing

- **The most common side effects** may include headache, weakness, nausea, vomiting, constipation, anxiety, problems sleeping, lightheadedness (dizziness), sleepiness, restlessness and rash.

What Should I Tell My Healthcare Professional?

Before you start taking [drug name], tell your healthcare professional if you:

- have or had heart problems
- have or had seizures
- have or had diabetes or increased blood sugar
- are trying to become pregnant, are already pregnant, or are breast-feeding
- drink alcohol

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with [drug name] review all medications that you are taking with your healthcare professional, including those that you take without a prescription.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following:

- blood pressure medicines
- ketoconazole
- quinidine
- carbamazepine
- fluoxetine or paroxetine

Avoid drinking alcohol while taking [drug name].

Is There Anything Else I Need to Know?

- [Drug name] may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how [drug name] affects you.
- It is important to avoid overheating and dehydration lower while taking [drug name]. [Drug name] may make it harder to lower your body temperature.

[Drug name] FDA Approved 2002
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Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
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