



## Patient Information Sheet

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### Paliperidone (marketed as Invega)

This is a summary of the most important information about Invega. For details, talk to your healthcare professional.

#### What Is Invega?

Invega Extended-Release Tablets are used to treat schizophrenia. Invega is an atypical antipsychotic medicine.

#### Who Should Not Use Invega?

You should not take Invega if you are allergic to paliperidone, risperidone or to any of the ingredients in Invega.

#### What Are The Risks?

*The following are the major potential risks and side effects of Invega therapy. However, this list is not complete.*

- **Increased chance of death and strokes in elderly patients with dementia.** Elderly patients with dementia who are treated with atypical antipsychotics, such as Invega, have a higher chance for death than patients who do not take these medicines. Invega is not approved to treat dementia.
- **QT prolongation (a serious heart problem).** Talk to your healthcare professional if you have or had any heart problems.
- **Neuroleptic malignant syndrome (NMS), a life-threatening nervous system problem.** 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. Get medical help right away if you have these symptoms.
- **Tardive dyskinesia (TD), a movement problem.** Uncontrollable, slow or jerky facial or body movements that may not go away. Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- **High blood sugar and diabetes.** These side effects may even lead to death in some patients. Patients with diabetes or those who have a higher chance for diabetes should have their blood sugar checked often.
- **Dizziness and fainting,** caused by a drop in blood pressure may happen with Invega, especially when you first start taking this medicine or when the dose is increased. Get up slowly when sitting or lying down.

- **Impaired judgment, thinking, or motor skills.** You should be careful when driving or using machines until you know how Invega affects you.
- **Overheating and dehydration.** Invega may make you more sensitive to heat. You may have trouble cooling off, or be more likely to become dehydrated. Be careful when exercising or doing activities in the heat.
- **Other serious side effects** may include: seizures, trouble swallowing, suicide, an erection that does not go away, and fever and bruising (thrombotic thrombocytopenic purpura).
- **Some common side effects** with Invega include: restlessness, involuntary movements, tremors and muscle stiffness, fast heart beat, headache, sleepiness, anxiety, dizziness, upset stomach and nausea.

**What Should I Tell My Healthcare Professional?**  
**Before you start taking Invega,** tell your healthcare professional if you:

- have or had heart problems
- have or have had seizures
- have or had diabetes or increased blood sugar
- have or had liver disease
- have or had problems with your esophagus, stomach or small or large intestine
- drink alcohol
- are pregnant, trying to become pregnant, or are breast-feeding.

Invega has not been studied in children under 18 years of age.

#### Can Other Medicines Or Food Affect Invega?

Invega and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Invega may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Especially tell your healthcare professional if you take:

- blood pressure medicines
- levodopa and medicines called dopamine agonists





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Avoid drinking alcohol while taking Invega.

#### How Should I Take Invega?

- Take Invega once a day in the morning.
- Swallow Invega tablets whole with water or other liquid. Do not chew, divide, or crush Invega tablets.
- Invega can be taken with or without food.

- The tablet shell will pass through your body and you may see it in your stool.

Date Approved: December 19, 2006

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