



## Patient Information Sheet

### Gefitinib (marketed as Iressa)

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

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**FDA ALERT [06/2005]: FDA has approved new labeling for Iressa that states the medicine should be used only in cancer patients who have already taken the medicine and whose doctor believes it is helping them. New patients should not be given Iressa because in a large study Iressa did not make people live longer. There are other medicines for non-small cell lung cancer (NSCLC) that have shown an ability to make people live longer.**

*This information reflects FDA's current analysis of all available data concerning this drug. FDA intends to update this sheet when additional information or analyses become available.*

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#### What Is Iressa?

- Iressa is a medicine used to kill cancer cells (chemotherapy). It is used alone for the continued treatment of patients who are benefiting or have benefited from Iressa. Iressa is approved for patients with non-small cell lung cancer (NSCLC) that:
  - has progressed after treatment with platinum based and docetaxel chemotherapies, or
  - did not respond to treatment with platinum based or docetaxel chemotherapies.

#### What Are The Risks?

*The following are the major possible risks and side effects of Iressa therapy. This list is not complete.*

- **Liver damage.**
- **Eye problems**, such as pain, redness or change in vision. Some patients have had an injury to the surface of the eye (cornea). This may be caused by eyelashes growing inside the eyelid.
- **Other side effects** with Iressa may include: diarrhea, rash, acne, dry skin, nausea, vomiting, itching, loss of appetite, weakness, weight loss

Before being treated with Iressa tell your healthcare professional if you:

- have or had liver problems.
- are trying to become pregnant, are already pregnant, or are breast-feeding

While being treated with Iressa call your healthcare professional right away if you develop:

- severe or continual diarrhea, nausea, vomiting, or loss of appetite. These conditions can lead to low body fluids (dehydration).
- an eye problem
- any new symptoms

#### Are There Any Interactions With Drugs or Foods?

Tell your healthcare professional about all the medicines you take, including prescription and over-the-counter drugs, and supplements. Especially tell your health care provider if you take:

- rifampicin, phenytoin
- warfarin
- ketoconazole, itraconazole
- ranitidine, cimetidine

These medicines may affect how Iressa works, or Iressa may affect how these medicines work.

**Iressa FDA Approved 2003  
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#### What Should I Tell My Healthcare Professional?



Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
Druginfo@cder.fda.gov