

Iressa
gefitinib

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Iressa?

Iressa is a medicine that contains the active substance gefitinib. It is available as brown tablets (250 mg).

What is Iressa used for?

Iressa is used to treat adults who have non-small cell lung cancer that is locally advanced or metastatic (when cancer cells have spread from the original site to other parts of the body). It is used in patients whose cancer cells have a mutation in the genes that make a protein called epidermal growth factor receptor (EGFR).

How is Iressa used?

Treatment with Iressa should be started and supervised by a doctor who has experience with anticancer treatments. The recommended dose is one tablet once a day. The tablet can be dispersed in water for patients who have difficulty swallowing.

How does Iressa work?

The active substance in Iressa, gefitinib, is a protein tyrosine kinase inhibitor. This means that it blocks specific enzymes known as tyrosine kinases. These enzymes can be found on the surface of cancer cells, such as EGFR on the surface of non-small cell lung cancer cells. EGFR is involved in the growth and spread of cancer cells. By blocking EGFR, Iressa helps to slow down the growth and spread of the cancer. Iressa works only in non-small cell lung cancer cells that have a mutation in their EGFR.

How has Iressa been studied?

The effects of Iressa were first tested in experimental models before being studied in humans. In one main study involving 1,217 adult patients with locally advanced or metastatic non-small cell lung cancer, Iressa was compared with a combination of carboplatin and paclitaxel (other anticancer medicines). The main measure of effectiveness was how long the patients lived without the disease getting worse.

In a second main study involving 1,466 patients with locally advanced or metastatic non-small cell lung cancer, Iressa was compared with docetaxel (another anticancer medicine). The main measure of effectiveness was survival (how long the patients lived). Both studies included patients with and without the EGFR mutation.

What benefit has Iressa shown during the studies?

In the first main study, Iressa was more effective at preventing the cancer from worsening than the combination. Among patients with the EGFR mutation, those who took Iressa lived for an average of nine and a half months without the disease getting worse, compared with about six months for those who took the combination therapy. In the second main study, patient survival among all patients who took Iressa was similar to those who took docetaxel.

What is the risk associated with Iressa?

The most common side effects with Iressa (seen in more than 1 patient in 10) are loss of appetite, diarrhoea, vomiting, nausea (feeling sick), stomatitis (inflammation of the lining of the mouth), increased level of alanine aminotransferase (a liver enzyme) in the blood, skin reactions such as pustular rash, and asthenia (weakness). There is also a risk of interstitial lung disease in patients taking Iressa. For the full list of all side effects reported with Iressa, see the Package Leaflet. Iressa should not be used in people who may be hypersensitive (allergic) to gefitinib or any of the other ingredients. It must not be used in mothers who are breastfeeding.

Why has Iressa been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Iressa's benefits are greater than its risks for the treatment of adults with locally advanced or metastatic non-small cell lung cancer with activating mutations of EGFR. The Committee recommended that Iressa be given marketing authorisation.

Other information about Iressa:

The European Commission granted a marketing authorisation valid throughout the European Union for Iressa to AstraZeneca AB on 24 June 2009.

The full EPAR for Iressa can be found [here](#).

This summary was last updated in 05-2009.