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# Tarceva (*erlotinib*)

An overview of Tarceva and why it is authorised in the EU

## What is Tarceva and what is it used for?

Tarceva is a cancer medicine used in non-small-cell lung cancer (NSCLC) that is advanced (the cancer has started to spread) or metastatic (it has already spread to other parts of the body). It is used for:

- previously untreated patients whose cancer cells have certain changes ('activating mutations') in the gene for a protein called epidermal growth factor receptor (EGFR);
- patients with EGFR activating mutations whose disease is stable after initial chemotherapy. Stable means that the cancer has neither improved nor worsened with chemotherapy (medicines to treat cancer);
- patients with EGFR activating mutations in whom previous chemotherapy has not worked;
- patients without EGFR activating mutations in whom previous chemotherapy has not worked and other treatments are unsuitable.

Tarceva is also used in patients with metastatic pancreatic cancer, in combination with gemcitabine (another cancer medicine).

The medicine contains the active substance erlotinib.

## How is Tarceva used?

Tarceva can only be obtained with a prescription and treatment should be supervised by a doctor who has experience in the use of cancer medicines. Patients with NSCLC should be tested for EGFR activating mutation before starting Tarceva, unless previous chemotherapy has not worked and other treatments are not suitable.

The medicine is available as tablets (25, 100 and 150 mg). For NSCLC, the usual dose is 150 mg daily. For pancreatic cancer, it is 100 mg daily. Tarceva is taken at least one hour before or two hours after food. If needed (for example because of side effects), the dose may be reduced in 50-mg steps. As Tarceva seems more effective in patients with pancreatic cancer who develop a rash, treatment should be re-assessed after 4 to 8 weeks if no rash has developed. Patients taking Tarceva should stop smoking, as smoking can decrease the amount of the medicine in the blood.

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For more information about using Tarceva, see the package leaflet or contact your doctor or pharmacist.

## How does Tarceva work?

The active substance in Tarceva, erlotinib, belongs to the group 'EGFR inhibitors'. Erlotinib blocks EGFRs, which can be found on some tumour cells. As a result of this block, the tumour cells can no longer receive the messages needed for growing and for spreading (metastasis). As a result, Tarceva helps to stop the cancer from growing and spreading through the body.

## What benefits of Tarceva have been shown in studies?

## NSCLC

In NSCLC, Tarceva has been mainly studied in four studies.

- The first study compared Tarceva with chemotherapy in 173 patients with advanced NSCLC with activating EGFR mutations who had not received previous chemotherapy. Patients taking Tarceva lived for an average of 10.4 months without their disease getting worse compared with 5.1 months for those receiving chemotherapy medicines.
- The second study compared Tarceva with placebo (a dummy treatment) in 889 patients with advanced or metastatic NSCLC whose disease had not got worse after 4 cycles of treatment with platinum-containing chemotherapy. Overall, Tarceva marginally increased how long patients lived without their disease getting worse and how long they survived. The greatest benefit was in a subgroup of 49 patients with EGFR activating mutations: those taking Tarceva (22 patients) lived for an average of 44.6 weeks without their disease getting worse, compared with 13 weeks for those taking placebo (27 patients).
- A third study compared Tarceva with placebo in 643 patients with advanced NSCLC whose cancer cells did not have EGFR activating mutations and whose disease was stable after 4 cycles of treatment with platinum-containing chemotherapy. The study compared how long patients survived when Tarceva was used early in the study with how long they survived when Tarceva was used later in the study. The study found no advantage to early use of the medicine, as patients treated with Tarceva early in the study did not live longer than those treated with Tarceva later in the study (after the disease had progressed).
- The fourth study compared Tarceva with placebo in 731 patients in whom at least one previous chemotherapy treatment had not worked. Patients taking Tarceva survived for an average of 6.7 months, compared with 4.7 months for the patients taking placebo. Among the patients who took Tarceva, the average survival was 8.6 months in those whose tumours were 'EGFR IHC-positive' (had EGFRs on the cell surface), and 5.0 months in those whose tumours were EGFR IHC-negative.

## Pancreatic cancer

Tarceva in combination with gemcitabine was studied in 569 patients with pancreatic cancer that was advanced, unresectable (that cannot be removed by surgery) or metastatic. Patients with metastatic cancer taking Tarceva as initial therapy lived without their disease getting worse for an average of 5.9 months, compared with 5.1 months in those taking placebo. However, there was no advantage for patients whose cancer had not spread beyond the pancreas.

## What are the risks associated with Tarceva?

In studies, the most common side effects with Tarceva when used as monotherapy for lung cancer were rash (affecting 75% of patients), diarrhoea (54%), loss of appetite and tiredness (52% each). In the study of Tarceva used in combination with gemcitabine for pancreatic cancer, the most common side effects were tiredness (affecting 73% of patients), rash (69%) and diarrhoea (48%). For the full list of side effects and restrictions with Tarceva, see the package leaflet.

## Why is Tarceva authorised in the EU?

Tarceva can prolong the time the patients live without their disease getting worse and prolong life in some patients. The side effects reported with Tarceva are considered manageable.

The European Medicines Agency therefore decided that Tarceva's benefits are greater than its risks and recommended that it be given marketing authorisation.

## What measures are being taken to ensure the safe and effective use of Tarceva?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tarceva have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tarceva are continuously monitored. Side effects reported with Tarceva are carefully evaluated and any necessary action taken to protect patients.

## Other information about Tarceva

Tarceva received a marketing authorisation valid throughout the EU on 19 September 2005.

Further information on Tarceva can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Tarceva.

This overview was last updated in 12-2018.