# Tarceva (erlotinib)
# Educational Material for Health Care Professionals for Dosing guidelines and Interstitial Lung Disease (ILD) Awareness and Management strategies

**Risk minimisation materials for Tarceva (erlotinib) are assessed by the EMA. These materials describe recommendations to minimise or prevent important risks of the drug.**


## Summary:

**Tarceva recommended daily dose is 150mg for non-small cell lung cancer (NSCLC) and 100mg in combination with gemcitabine for pancreatic cancer. If dose reduction is necessary, this should be carried out in 50mg steps.**

**Current smokers should be advised to stop smoking and concomitant use of potent CYP3A4 inducers or inhibitors should be avoided.**

**In case of acute or progressive unexplained pulmonary symptoms, Tarceva should be interrupted and diagnostically evaluated. Upon ILD diagnosis, Tarceva should be discontinued.**


**Please read this information carefully before prescribing this product. This recommendation should not substitute for independent medical judgment.**

## Indications[1]

### Non-Small-Cell Lung Cancer (NSCLC)

- Tarceva is indicated for the first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR activating mutations
- Tarceva is also indicated for switch maintenance treatment in patients with locally advanced or metastatic NSCLC with EGFR activating mutations and stable disease after first-line chemotherapy
- Tarceva is also indicated for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

### Pancreatic Cancer

- Tarceva in combination with gemcitabine is indicated for treatment of patients with metastatic pancreatic cancer.

## Dosing guidelines[1]

- Tarceva exists in three tablet strengths: 150mg, 100mg, 25mg.
- The recommended daily dose of Tarceva is
  - NSCLC: 150mg daily
  - pancreatic cancer: 100mg daily, in combination with gemcitabine
- EGFR mutation testing should be performed prior to initiation of Tarceva therapy in chemo-naïve patients with advanced or metastatic NSCLC.
- Tarceva should be taken orally ***at least 1 hour before or 2 hours after the ingestion of food***. Patients should be advised to contact their doctor or pharmacist if they miss one or more doses of Tarceva. The dose should not be doubled to make up for forgotten doses.
- While receiving Tarceva, current smokers should be advised to stop smoking.
- Women of child-bearing potential must be advised to avoid pregnancy while taking Tarceva.
- The concomitant use of potent CYP3A4 inducers or inhibitors should be avoided.
- If patients experience intolerable toxicity that cannot be managed medically, consider dose reduction, interruption or discontinuation. If dose reduction is necessary, this should be carried out in 50mg steps.

## Interstitial Lung Disease: frequency, risk factors, diagnosis and treatment:

## Frequency of ILD-Like Events:

ILD-like events, including fatalities, have been reported uncommonly in patients receiving Tarceva (overall incidence of less than 1%). A higher incidence of ILD-like events (approximately 5% with a mortality rate of 1.5%) has been seen in Japan.

## Risk factors:

Concomitant or prior chemotherapy, prior radiotherapy, pre-existing parenchymal lung disease, metastatic lung disease, or pulmonary infections.

## Diagnosis and Treatment:

- In patients who develop acute onset of new and/or progressive unexplained pulmonary symptoms such as dyspnoea, cough and fever, Tarceva should be interrupted pending diagnostic evaluation.
- Patients treated concurrently with Tarceva and gemcitabine should be monitored carefully for the possibility to develop ILD-like toxicity.
- If ILD is diagnosed, Tarceva should be discontinued and appropriate treatment initiated as necessary.

### References

1. Tarceva® (erlotinib) Summary of Product Characteristics. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000618/human_med_001077.jsp&mid=WC0b01ac058001d124

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal

Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

This educational material is provided by Roche Products Ltd. and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.