Tarceva: Dosing Guidelines & Side-Effect Management Strategies

This short leaflet provides practical guidance on the use of Tarceva (erlotinib). For full details, please refer to the Summary of Product Characteristics.[1]

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
  - as monotherapy for maintenance treatment in patients with locally advanced or metastatic NSCLC with stable disease after 4 cycles of standard platinum-based first-line chemotherapy
  - 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 (see Summary of Product Characteristics for gemcitabine).
- 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.

Adverse events[1]

- Interstitial lung disease (ILD)-like events occur uncommonly and, if confirmed, necessitate discontinuation of Tarceva. Management of ILD-like events is described below.

Management of ILD-Like Events

- ILD-like events, including fatalities, have been reported uncommonly in patients receiving Tarceva (overall incidence of approximately 0.6%). A higher incidence of ILD (approximately 5% with a mortality rate of 1.5%) is seen among patients with Japanese origin.
- Confounding or contributing factors such as concomitant or prior chemotherapy, prior radiotherapy, pre-existing parenchymal lung disease, metastatic lung disease, or pulmonary infections were frequent.
- 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.

This recommendation should not substitute for independent medical judgement.

References:

1. Tarceva® (erlotinib) Summary of Product Characteristics. Access via: www.medicines.org.uk/emc/

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 and sent by email to postlicensing.medicinesauthority@gov.mt or posted to ADR Reporting, The Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA.

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.

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