Tarceva® (erlotinib): dosing guidelines and side-effect management strategies

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

Indications

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***[1]
  - 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.

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Adverse events

- Rash and diarrhoea are two of the most commonly reported adverse drug reactions, which are mostly grade 1 or 2 in severity[1]
  - more severe reactions can occur, necessitating active management, dose modification or discontinuation.[1–4]
- Interstitial lung disease (ILD)-like events occur uncommonly and, if confirmed, necessitate discontinuation of Tarceva (see below).
- The information below summarises potential approaches to the management of selected adverse events. While this information has been diligently retrieved from the literature, it should not be viewed as a recommendation from Roche, or considered a substitute for independent medical judgement.

Management of rash

- The following prophylactic measures may be considered in all patients[2,3]
  - use of a high-factor sunscreen when outdoors
  - avoid excessive exposure to water and soap, and use a thick, alcohol-free emollient cream containing urea or lactic acid.
- Although there are no evidence-based recommendations for the management of rash, several approaches have been used[2–4]
  - the most commonly proposed strategies involve the use of topical or systemic antibiotics or corticosteroids.
- If severe reactions do not improve or are intolerable, dose modification, interruption or discontinuation may be necessary[1–5]
  - referral to a dermatologist may also be considered.

Management of diarrhoea

- Diarrhoea of grade 2 or higher may be managed by administration of standard antidiarrhoeal treatment[1]
  - loperamide 4mg should be given at first onset, followed by 2mg every 2–4 hours until the patient is diarrhoea-free for 12 hours.[6]
  - appropriate rehydration should be provided, and electrolytes replaced if necessary.[1]
- Patients with severe diarrhoea that is unresponsive to loperamide, or those with associated dehydration, may require dose reduction, interruption or discontinuation.[1]

Management of ILD-like events[1]

- ILD-like events, including fatalities, have been reported uncommonly in patients receiving Tarceva (overall incidence of approximately 0.6%)
  - confounding or contributing factors are 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
  - if ILD is diagnosed, Tarceva should be discontinued and appropriate treatment initiated as necessary.

References

1. Tarceva® (erlotinib) Summary of Product Characteristics, Roche Registration Ltd
2. Reck M, Gutzmer R. Management of the cutaneous side effects of therapeutic epidermal growth factor receptor inhibition. Onkologie 2010;33:470–9.
3. Gridelli C, et al. Clinical significance and treatment of skin rash from erlotinib in non-small cell lung cancer patients: results of an expert panel meeting. Crit Rev Oncol Hematol 2008; 66:155–62.
4. Lacouture ME, et al. Clinical practice guidelines for the prevention and treatment of EGFR inhibitor-associated dermatologic toxicities. Support Care Cancer 2011; 19:1079–95.
5. Segaert S. Management of skin toxicity of epidermal growth factor receptor inhibitors. Targ Oncol 2008; 3:245–51.
6. Wadler, S et al. Recommended Guidelines for the Treatment of Chemotherapy-Induced Diarrhea. Journal of Clinical Oncology 1998; 16: 3169-178

Suspected adverse reactions associated with the use of Tarceva should be reported to:

Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, or at: http://www.medicinesauthority.gov.mt/pub/adr.doc

Healthcare professionals may also report any adverse events suspected to be associated with the use of Tarceva to Roche by phone on UK +44 1707 367554, by fax on UK +44 1707 367582 or e-mail at welwyn.uk_dsc@roche.com

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