

25 May 2009

Addressee

Important Safety Information on Tarceva[®] ▼ (erlotinib)

Dear Health Care Professional

Subject: Information on the association of erlotinib (Tarceva) with gastrointestinal perforation

Summary

- Patients receiving Tarceva are at increased risk of developing gastrointestinal perforations.
- Patients receiving concomitant anti-angiogenic agents, corticosteroids, NSAIDs and/or/taxane based chemotherapy, or who have prior history of peptic ulceration or diverticular disease are at increased risk.
- Tarceva should be permanently discontinued in patients who develop gastrointestinal perforation.
- The Product information will be updated accordingly.

The Summary of Product Characteristics will also be updated with information on bullous, blistering and exfoliative skin conditions including very rare cases (less than 1 per 10,000 patients) suggestive of Stevens-Johnson syndrome/Toxic epidermal necrolysis. Furthermore, information on corneal perforation or ulceration (less than 1 per 10,000 patients) will be added.

This information has been endorsed by the Committee for Medicinal Products for Human Use (CHMP).

Information on the safety concern

Roche Products Limited would like to inform you of important new safety information regarding use of Tarceva (erlotinib).

Erlotinib is an epidermal growth factor receptor (EGFR, also known as HER1) tyrosine kinase inhibitor. Tarceva is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. In combination with gemcitabine, Tarceva is also indicated for the treatment of patients with metastatic pancreatic cancer.

Roche has evaluated signals pertaining to gastrointestinal disorders, skin toxicities and ocular disorders. Based on those evaluations, Roche would like to inform you of the following new Warnings and Precautions:

Gastrointestinal Perforation: Patients receiving Tarceva are at increased risk of developing gastrointestinal perforation, which was observed uncommonly. Patients receiving concomitant anti-angiogenic agents, corticosteroids, NSAIDs, and/or taxane based chemotherapy, or who have prior history of peptic ulceration or diverticular disease are at increased risk. Tarceva should be permanently discontinued in patients who develop gastrointestinal perforation.

Bullous and exfoliative skin disorders: Bullous, blistering and exfoliative skin conditions have been reported, including very rare cases suggestive of Stevens-Johnson syndrome/Toxic epidermal necrolysis, which in some cases were fatal. Tarceva treatment should be interrupted or discontinued if the patient develops severe bullous, blistering or exfoliating conditions.

Ocular Disorders: Very rare cases of corneal perforation or ulceration have been reported during use of Tarceva. Other ocular disorders including abnormal eyelash growth, keratoconjunctivitis sicca or keratitis have been observed with Tarceva treatment which are also risk factors for corneal perforation/ulceration. Tarceva therapy should be interrupted or discontinued if patients present with acute/worsening ocular disorders such as eye pain.

Roche is currently updating the SmPC and Package Leaflet to reflect this information accordingly.

The information contained in this letter has been reviewed and endorsed by the Committee for Medicinal Products for Human Use (CHMP).

Any occurrence of serious and/or unexpected adverse reactions in patients receiving Tarceva should be reported.

Any suspected adverse reaction should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using a Yellow Card available directly from the MHRA, CHM Freepost, London SW8 5BR or electronically via the MHRA website at <http://www.yellowcard.gov.uk>

Any suspected adverse reaction should also be reported to Roche Products Limited, by phone on 01707 367554, by fax on 01707 367582 or e-mail at welwyn.uk_dsc@roche.com.

Should you have any questions or require additional information regarding the use of Tarceva, please contact Roche Medical Information on 0800 3281629 or 01707 361 010 or e-mail at Medinfo.uk@roche.com.

Yours sincerely,



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