

Tarceva dosing information



Tarceva is indicated for the treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) after failure of at least one prior chemotherapy regimen.

For full indication, please see enclosed summary of product characteristics.



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Dosage and administration

- The recommended daily dose of Tarceva is 150 mg.¹
- Tarceva should be taken orally at least one hour before or two hours after the ingestion of food.¹
- Tarceva is available in strengths of 150 mg, 100 mg and 25 mg.*¹

*25-mg tablet not available in all countries.

Precautions with Tarceva

- Women of childbearing potential must be advised to avoid pregnancy while on Tarceva.¹
- Current smokers should be advised to stop smoking, as plasma concentrations could be reduced.¹

Modifications with dosing

- When dose adjustment is necessary, reduce in 50-mg steps.¹
- Six percent and 1% of patients needed dose reduction for rash and diarrhea, respectively.¹
- The Tarceva pivotal trial specified the following dose modification guidelines for Grade ≥ 3 rash or diarrhea that could not be medically managed:^{2,3}
 - hold the dose until symptom returned to Grade ≤ 1 ²
 - reduce the dose by a 50-mg step¹

Favorable tolerability profile

- The most common adverse drug reactions in patients receiving Tarceva were rash and diarrhea. In the pivotal trial, Grade 3/4 rash and diarrhea occurred in 9% and 6%, respectively, of Tarceva-treated patients.¹
- Patients with mild/tolerable (Grade 1), moderate/tolerable (Grade 2) or severe/intolerable (Grade ≥ 3) reactions may be appropriate for treatment with medically managed supportive care.^{2,3}
- Patients with Grade ≥ 3 reactions or those that cannot be managed medically may require a dose reduction or temporary interruption of Tarceva treatment.^{2,3}
- In the pivotal trial, most patients tolerated the 150-mg dose. Rash and diarrhea each resulted in study discontinuation in 1% of Tarceva-treated patients.¹

Concomitant use with CYP3A4 inhibitors and inducers

- Co-treatment with the CYP3A4 inducer rifampicin decreased erlotinib AUC by 69%. Alternate treatments lacking CYP3A4 inducing activity should be considered.¹
- Co-treatment with the potent CYP3A4 inhibitor ketoconazole increases erlotinib AUC by 86%. Caution should be used when administering or taking Tarceva with ketoconazole or other strong CYP3A4 inhibitors.¹
- Concomitant use of CYP3A4 substrates and modulators may require dose adjustment.¹



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Tarceva (erlotinib) tablets, 150 mg

Round, biconvex, film-coated tablets with 'Tarceva 150' and logo printed in brown on one side.



Tarceva (erlotinib) tablets, 100 mg

Round, biconvex, film-coated tablets with 'Tarceva 100' and logo printed in grey on one side.



Tarceva (erlotinib) tablets, 25 mg*

Round, biconvex, film-coated tablets with 'Tarceva 25' and logo printed in brownish yellow on one side.

*25-mg tablet not available in all countries.



All 3 strengths are supplied in a foil-backed PVC blister containing 30 tablets.

References: 1. Tarceva® (erlotinib) summary of product characteristics. F. Hoffmann-La Roche Ltd., 2005. 2. Shepherd FA, Pereira JR, Ciuleanu T, et al, for the National Cancer Institute of Canada Clinical Trials Group. Erlotinib in previously treated non-small-cell lung cancer. *N Engl J Med.* 2005;353:123-132. 3. Data on file, OSI Pharmaceuticals, Inc.



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 **Tarceva**[®]
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