



A fact sheet for patients

Taking action in first-line advanced pancreatic cancer

Indication: Tarceva in combination with gemcitabine is indicated for first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

Please see important safety information on inside cover and accompanying full prescribing information.

 **Tarceva**[®]
erlotinib
tablets

Safety information

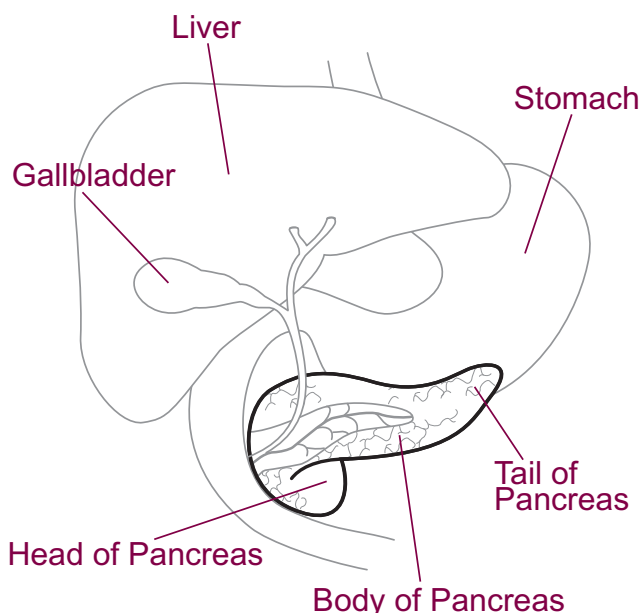
Important safety information

- There have been infrequent reports of serious Interstitial Lung Disease (ILD)-like events, including fatalities, in patients receiving Tarceva for treatment of NSCLC, pancreatic cancer or other advanced solid tumors.
- Cases of hepatic failure, hepatorenal syndrome, acute renal failure (all including fatalities), and renal insufficiency have been reported during use of Tarceva.
- Gastrointestinal perforation (including fatalities) has been reported in patients receiving Tarceva.
- Bullous, blistering and exfoliative skin conditions have been reported including cases suggestive of Stevens-Johnson syndrome/toxic epidermal necrolysis, which in some cases were fatal.
- In the pancreatic cancer trial, other serious adverse reactions associated with Tarceva plus gemcitabine and which may have included fatalities, were myocardial infarction/ischemia, cerebrovascular accident and microangiopathic hemolytic anemia with thrombocytopenia.
- Corneal perforation and ulceration have been reported during use of Tarceva.
- When receiving Tarceva therapy, women should be advised against becoming pregnant or breastfeeding. Tarceva is pregnancy category D.
- The most common adverse reactions in patients with pancreatic cancer receiving Tarceva 100 mg plus gemcitabine were fatigue, rash, nausea, anorexia and diarrhea.

Please see accompanying full prescribing information.

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The pancreas sits behind your stomach. It makes enzymes that digest food and hormones (such as insulin) that balance blood sugar.

Taking Tarceva® (erlotinib) tablets for pancreatic cancer

- Tarceva is a prescription pill you take by mouth once a day.
- In pancreatic cancer, Tarceva is given with gemcitabine, a chemotherapy drug.
- **Do not take Tarceva with food.** Tarceva should be taken at least one hour before or two hours after eating.¹
- Taking Tarceva may cause a rash in some patients; the following details may help.



How likely am I to get a rash from taking Tarceva?

- Skin rash is one of the most common side effects from taking Tarceva. Not everyone gets a rash, but many people do.
- If you do get a rash, it will most likely appear within 8 to 10 days of starting Tarceva, but you can get a rash at any time during your treatment.¹
- If you get a rash while taking Tarceva, call your doctor or nurse, but **do not stop taking Tarceva unless your doctor tells you to stop.**

What is the rash like?

- Most rash is mild to moderate and is usually on the head or upper body.²
- It may look like acne, but it is not, so **do not use over-the-counter acne medicine on this rash.** Some acne medicines may make the rash worse.²

How can I help manage the rash?²

- Use a mild soap (such as Vanicream™, Dove®, Cetaphil®, or _____).
- Keep your skin moisturized. It may be okay to use makeup.
- Stay out of the sun when you can, and use sunscreen with an SPF of 15 or higher.
- Follow your doctor's and/or nurse's advice on managing any rash.

Please see the full indication and important safety information on the back and the accompanying full prescribing information.

If you have questions

Oncologist: _____ Phone: _____

Nurse: _____ Phone: _____

Notes: _____

Indication

Tarceva in combination with gemcitabine is prescribed for patients who have not received previous chemotherapy for locally advanced pancreatic cancer, pancreatic cancer that cannot be surgically removed, or pancreatic cancer that has spread to distant body organs.

Important safety information

In clinical studies, there were infrequent reports of serious lung injuries similar to Interstitial Lung Disease (ILD)-like events. Reports of ILD-like events have been serious and have included deaths in patients taking Tarceva.

Liver and/or kidney problems (including deaths) have been reported in some patients taking Tarceva. Let your doctor know if you have a history of liver or kidney disease.

Holes that formed in the stomach, small intestine, or large bowel (including deaths) have been reported in patients taking Tarceva.

Severe blistering skin reactions including cases similar to Stevens-Johnson syndrome (including deaths) have been reported in patients taking Tarceva.

Patients taking Tarceva plus gemcitabine were more likely to experience bleeding and clotting problems such as heart attack or stroke.

Eye swelling, infection, and holes in the cornea have been reported in patients taking Tarceva.

Tarceva may cause harm to an unborn baby or may cause possible risk of pregnancy loss. Women should avoid becoming pregnant and avoid breastfeeding while taking Tarceva.

You should call your doctor right away if you have these signs or symptoms: new or worsening skin rash; serious or ongoing diarrhea, nausea, loss of appetite, vomiting, or stomach pain; new or worsening shortness of breath or cough; fever; eye irritation.

If you smoke, you should stop smoking while taking Tarceva, as it may affect how well Tarceva works for you. If you continue to smoke, you should speak to your doctor before taking Tarceva.

Let your doctor know if you are taking other prescription or over-the-counter drugs or herbal supplements before you start taking Tarceva. While taking Tarceva, do not start taking any new drugs or herbal supplements before talking to your doctor. Do not eat grapefruit or drink grapefruit juice while taking Tarceva. Tarceva may also affect other medications you are taking.

Fatigue, rash, nausea, loss of appetite, and diarrhea were the most common side effects associated with Tarceva plus gemcitabine therapy in a large clinical study.

Tarceva is not right for everyone. Ask your doctor if once-daily Tarceva is right for you.

Please see the accompanying full prescribing information for additional safety information.

For further information, please visit our Web site at www.tarceva.com.

References: 1. Tarceva [package insert]. Melville, NY: OSI Pharmaceuticals Inc; 2009. 2. Lacouture ME. Tips to help with EGFR targeted therapy skin changes. Supplemental data to: Lynch TJ Jr, Kim ES, Eaby B, Garey J, West DP, Lacouture ME. Epidermal growth factor receptor inhibitor-associated cutaneous toxicities: an evolving paradigm in clinical management. *Oncologist*. 2007;12(5):610-621.

