

PRODUCT MONOGRAPH

Pr **TARCEVA**[®]

erlotinib hydrochloride tablets

erlotinib 25, 100, 150 mg

Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor

Protein Kinase Inhibitor

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario, Canada
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www.rochecanada.com

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PART III: CONSUMER INFORMATION**PrTARCEVA®
(erlotinib hydrochloride tablets)**

This leaflet is part III of a three-part "Product Monograph" published when TARCEVA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TARCEVA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

TARCEVA is prescribed to you because you have non-small cell lung cancer at an advanced stage and;

- chemotherapy has not helped to stop your disease or
- your cancer cells have certain changes in the gene for a protein called epidermal growth factor receptor (EGFR) and your disease has not worsened after 4 cycles of first line chemotherapy, or
- your cancer cells have certain changes in the EGFR gene.

What it does:

TARCEVA belongs to a group of medicines called epidermal growth factor receptor tyrosine kinase inhibitors which are used to treat cancer. TARCEVA prevents the activity of a protein called epidermal growth factor receptor. This protein is known to be involved in the growth and spread of cancer cells.

When it should not be used:

Do not take TARCEVA if you are hypersensitive (allergic) to erlotinib or any of the other ingredients of TARCEVA. See *What the nonmedicinal ingredients are*.

What the medicinal ingredient is:

Erlotinib (as erlotinib hydrochloride)

What the nonmedicinal ingredients are:**Tablet core:**

Lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, sodium lauryl sulfate.

Tablet coating:

Hydroxypropyl cellulose, hydroxypropyl methyl cellulose, polyethylene glycol, titanium dioxide.

What dosage forms it comes in:

- Tablets
- Each tablet contains 25, 100 or 150 mg erlotinib as erlotinib hydrochloride.

TARCEVA is a white to yellowish, round, film-coated tablet and is available in pack sizes of 30 tablets.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

TARCEVA should be prescribed and managed only by a doctor who is experienced with anticancer drugs.

You must have a confirmed activating mutation of the EGFR-TK prior to starting of first-line TARCEVA monotherapy

TARCEVA has not been studied in patients with severely reduced liver function

TARCEVA has not been studied in patients with severely reduced kidney function

Serious side effects that have been reported with TARCEVA include:

- liver failure, including fatal cases
- gastrointestinal perforation (a hole through the wall of the stomach or small intestine, or large bowel), including fatal cases.

BEFORE you use TARCEVA talk to your doctor or pharmacist if:

- you have liver problems
- you have kidney problems
- you have gastrointestinal ulcers (bleeding of the stomach or intestines) or diverticular disease
- you have cataracts, have had cataract surgery, or wear contact lenses
- you have lung disease
- you smoke tobacco
- you plan to become pregnant
- you plan to breastfeed. Breastfeeding should be avoided while being treated with TARCEVA and for at least 2 weeks after the final dose.
- you have been told by your doctor that you cannot tolerate some sugars

Avoid pregnancy while being treated with TARCEVA. If you are a woman who could become pregnant, use adequate contraception during treatment and for at least 2 weeks after taking the last tablet. If you become pregnant while you are being treated with TARCEVA, immediately inform your doctor who will decide if the treatment should be continued.

Smoking tobacco may reduce TARCEVA blood level.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking other drugs, including non-prescription and natural health products, because they may speed up or slow down the breakdown of TARCEVA. For example:

- Antifungals (such as ketoconazole, fluconazole)
- Calcium channel blockers (such as diltiazem, verapamil)
- Macrolide antibiotics (such as erythromycin, clarithromycin)
- Fluoroquinolone antibiotics (such as ciprofloxacin, norfloxacin)
- Other antibiotics such as rifampin

- Some antivirals (such as ritonavir, indinavir)
- Grapefruit juice
- St. John's Wort
- Anticonvulsants such as carbamazepine and phenytoin
- Blood thinners such as warfarin
- Medications which reduce acid in the stomach (such as omeprazole, ranitidine)
- Statin drugs to treat high cholesterol

PROPER USE OF THIS MEDICATION

Usual dose:

The usual dose is one 150 mg tablet each day.

Take your TARCEVA tablet:

- at least 1 hour before you eat or
- at least 2 hours after you have eaten

If you are taking medications which reduce acid in the stomach (such as ranitidine 150 mg twice a day), take your TARCEVA tablet:

- 2 hours before your morning dose of the medication and
- 10 hours after your evening dose of the medication

Swallow your tablet with a glass of plain water.

Always take TARCEVA exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure. This medicine has been prescribed for you personally and should not be passed on to others. It may harm them even if their symptoms are the same as yours.

Overdose:

In case of an overdose or suspected overdose, contact your doctor, hospital emergency department or the regional poison control centre.

Missed Dose:

If you miss one or more doses of TARCEVA, contact your doctor or pharmacist as soon as possible.

Do not take a double dose to make up for forgotten individual doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, TARCEVA can have side effects.

The most common side effects (more than 5 out of 10 patients):

- rash
- diarrhea

If diarrhea occurs, drink plenty of water throughout the day to reduce the risk of dehydration. If you are having difficulty drinking liquid due to severe nausea/vomiting, please call your doctor immediately to be assessed for possible dehydration, low potassium levels and kidney failure.

Very common side effects (more than 1 out of 10 patients): tiredness, loss of appetite, difficulty in breathing, cough, infection, nausea, vomiting, mouth irritation, stomach pain, itching, dry skin, eye irritation.

Common side effects (less than 1 out of 10 patients):

- Bleeding from the stomach or the intestines
- Abnormal blood tests for the liver function.
- Headaches and dizziness
- Hair and nail changes. They included inflammatory reactions around the fingernail (common), excess body and facial hair of a male distribution pattern (uncommon), eyelash and eyebrow changes (uncommon), and brittle and loose nails (uncommon)
- Acne or other red or pink little bumps at hair follicles

Contact your doctor as soon as possible if you suffer from any of the above side effects.

Uncommon serious side effects (less than 1 out of 100 patients):

- Interstitial lung disease, a rare form of lung inflammation and can have a fatal outcome in some cases. If you develop symptoms such as sudden difficulty of breathing associated with cough or fever contact your doctor immediately
- Gastrointestinal bleeding or perforation (a hole through the entire wall of stomach, intestine, or bowel)
- Corneal perforation, the risk is higher in patients who have had cataract surgery or wear contact lenses
- severe skin reactions (Stevens-Johnson Syndrome)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist	
	Only if severe	In all cases		
Most common (> 5 / 10 patients)	rash		✓	
	diarrhea		✓	
	loss of appetite		✓	
	difficulty in breathing		✓	
	cough		✓	
	infection		✓	
	vomiting		✓	
	nausea		✓	
stomach pain		✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
Common (<1/10 patients)	bleeding from stomach or intestine		✓	
	abnormal tests for liver function		✓	
Uncommon (<1/100 patients)	interstitial lung disease (sudden difficulty in breathing associated with cough or fever)		✓	
	gastrointestinal perforation (abdominal pain-severe, fever, nausea and vomiting)		✓	
	corneal perforation (eye pain, worsening of vision or loss of vision)		✓	
	severe skin reactions (skin rash, discolouration, blistering, or pain)		✓	

This is not a complete list of side effects. For any unexpected effects while taking TARCEVA, contact your doctor or pharmacist.

HOW TO STORE IT

Store TARCEVA between 15-30°C.
 Keep out of the reach of children.
 Do not use after the expiry date stated on the carton.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online: www.healthcanada.gc.ca/medeffect

Call toll-free at; 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789
- Mail to: Canada Vigilance Program
 Health Canada
 Postal Locator 1908C
 Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health care provider. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Hoffmann-La Roche Limited, at 1-888-762-4388, or at www.rochecanada.com

This leaflet was prepared by Hoffmann-La Roche Limited, Mississauga, L5N 5M8

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