CONSUMER INFORMATION
Product Monograph Part III

TARCEVA™
erlotinib
25, 100, and 150 mg tablets

Hoffmann-La Roche Limited

Submission Control No. 094813

The Consumer Information Section (Part III) of the Product Monograph for TARCEVA has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on July 7, 2005 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION

TARCEVA™
(erlotinib as erlotinib hydrochloride)

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. 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.

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.

If you have been told by your doctor that you cannot tolerate some sugars, contact your doctor before taking TARCEVA.

What dosage forms it comes in:
25 mg, 100 mg and 150 mg tablets.

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

WARNINGS AND PRECAUTIONS

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

- you have liver problems
- you plan to become pregnant
- you plan to breastfeed.
- you are taking or have recently taken any other medicines, even those not prescribed

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.

Do not breastfeed if you are being treated with TARCEVA.

Ask your doctor or pharmacist for advice before taking any medicine.

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)
- Some antivirals (such as ritonavir, indinavir)
- Grapefruit juice.

In some cases these drugs may increase the side effects of TARCEVA and your doctor may need to adjust your treatment.

If you take blood thinners (like warfarin or other coumarin derivatives), tell your doctor because TARCEVA may increase your risk of bleeding and your doctor will need to regularly monitor you with blood tests.

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

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.

It is not known whether TARCEVA has a different effect if your liver is not functioning normally.

Overdose:
If you take more TARCEVA than you should: Contact your doctor or pharmacist immediately.
You may have increased side effects and your doctor may interrupt your TARCEVA treatment.

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.

It is important to keep taking TARCEVA every day, as long as your doctor prescribes it for you.

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) are rash and diarrhea.

Other very common side effects (more than 1 out of 10 patients) include 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) are bleeding from the stomach or the intestines and abnormal blood tests for the liver function.

Contact your doctor as soon as possible if you suffer from any of the above side effects. In some cases your doctor may need to add a medication to treat the side effect, reduce your dose of TARCEVA or interrupt treatment.

An uncommon serious side effect (less than 1 out of 100 patients) is a rare form of lung irritation called interstitial lung disease. This disease can also be linked to the natural progression of your medical condition 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. Your doctor may decide to permanently stop your treatment with TARCEVA.
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			
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)		✓	

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

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345
toll-free fax: 866-678-6789
By email: cadrmp@hc-sc.gc.ca

By regular mail:
National AR Centre
Marketed Health Products Safety and Effectiveness Information Division
Marketed Health Products Directorate
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

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

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