

**PART III: CONSUMER INFORMATION**

**PrTYKERB®  
Lapatinib tablets  
(as lapatinib ditosylate)**

This leaflet is part III of a three-part "Product Monograph" published when TYKERB® (lapatinib ditosylate) tablets were approved for sale in Canada, and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TYKERB. Contact your doctor or pharmacist if you have any questions about the drug.

**What dosage forms it comes in:**

TYKERB is provided as a yellow, oval, biconvex film-coated tablet with "GS XJG" engraved on one side.



Each tablet contains 250 mg lapatinib as lapatinib ditosylate monohydrate.

**ABOUT THIS MEDICATION**

**What the medication is used for:**

TYKERB is used in combination with capecitabine for the treatment of patients with metastatic breast cancer that is ErbB2 (HER2) positive. The combination treatment is indicated for women whose breast cancer has progressed after treatment with a taxane, and an anthracycline. In addition, their metastatic breast cancer should have progressed during treatment with trastuzumab.

TYKERB in combination with capecitabine has been shown to delay progression of breast cancer. It has not been proven to increase your survival or reduce the symptoms associated with your breast cancer.

TYKERB is used in combination with letrozole for the treatment of post-menopausal patients with hormone receptor positive metastatic breast cancer, whose tumours overexpress the ErbB2 (HER2) receptor, and who are suitable for endocrine therapy.

**What it does:**

TYKERB is a kinase inhibitor which interferes with the growth of certain tumour cells.

**When it should not be used:**

TYKERB must not be used if you are allergic to lapatinib ditosylate, or any of the other ingredients in TYKERB (see *What the important nonmedicinal ingredients are*).

**What the medicinal ingredient is:**

Lapatinib ditosylate monohydrate.

**What the important nonmedicinal ingredients are:**

TYKERB tablets contain the following nonmedical ingredients: hypromellose, iron oxide red, iron oxide yellow, macrogol/PEG 400, magnesium stearate, microcrystalline cellulose, polysorbate 80, povidone, sodium starch glycolate and titanium dioxide.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

TYKERB should be prescribed and managed by a doctor experienced in anticancer drugs. Serious side effects of TYKERB include:

- Liver toxicity can be severe and deaths have happened (harmful effect on the liver)
- Decreased left ventricular ejection fraction (decreased pumping of blood from the left ventricle of the heart)
- Abnormal heartbeat (QT prolongation)
- Severe diarrhea, which can be life-threatening

BEFORE you use TYKERB, talk to your doctor or pharmacist if:

- You have or have had heart problems, such as abnormal heartbeat (arrhythmias or dysrhythmias) or fainting spells
- You have electrolyte disturbances, such as low blood potassium, low blood magnesium, low blood calcium, or conditions that could lead to electrolyte disturbances such as eating disorder, vomiting, diarrhea, dehydration, diabetes (with nerve disorders)
- You have a family history of sudden cardiac death at younger than 50 years of age
- You have lung problems
- You have liver problems
- You have diarrhea or any changes in bowel patterns
- You are pregnant, or are planning to become pregnant
- You are breastfeeding or are planning to do so

TYKERB may cause harm to your unborn baby. Therefore, you should use effective methods of contraception while taking TYKERB and for at least 5 days after stopping TYKERB. Ask your doctor about effective contraception options. If you become pregnant during treatment with TYKERB, tell your doctor immediately. It is not known whether TYKERB passes into breast milk, therefore do not breast-feed while taking TYKERB and for 5 days after the last dose as it may harm your baby.

TYKERB has an effect on the electrical activity of the heart known as QT/QTc prolongation. This may lead to disturbances in the heartbeat (heart rhythm) that could result in dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting (syncope) or death. These heart rhythm disturbances are more likely in patients with risk factors, such as heart problems, taking medicines that affect the heart, being female or being over 65 years of age. It is important to follow the instructions of your doctor with regard to dosing or any special tests. If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should seek immediate medical attention.

Safety and efficacy of TYKERB have not been established in children.

TYKERB can make you feel drowsy or sleepy.

- Don't drive or use machines unless you are sure you are not affected.

### **Severe Skin Reactions**

Severe skin reactions have been seen with TYKERB. Symptoms may include skin rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever or any combination of these. Tell your doctor as soon as possible if you get any of these symptoms. As severe skin reactions can be life threatening, your doctor may tell you to stop taking TYKERB.

TYKERB may increase the risk of photosensitivity. You are encouraged to avoid exposure to sunlight and apply broad spectrum sunscreens with an SPF  $\geq 30$  if exposure to sunlight cannot be avoided.

## **INTERACTIONS WITH THIS MEDICATION**

There are certain groups of medicines that interact with TYKERB. The following list includes some, but not all, medicines that interact with TYKERB. Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes non-prescription medicines, vitamins, and natural health products.

- drugs used to treat infections (antibiotics and anti-fungals)
- drugs used to treat HIV (AIDS)
- drugs used to treat chronic inflammation or asthma (steroids)
- drugs used to treat seizures (anticonvulsant drugs)
- drugs used to treat certain heart disorders and high blood pressure (calcium channel blockers)
- water pills (diuretics)
- opioids (e.g. methadone)

- antidepressants
- antipsychotics
- drugs that decrease stomach acidity (used to treat stomach ulcers or indigestion)
- herbal products (St. John's Wort)

You should also avoid grapefruit juice or products containing grapefruit juice.

**Because TYKERB is given with another drug, either capecitabine or letrozole, you should also discuss with your doctor any medicines that should be avoided when taking capecitabine (Xeloda\*) or letrozole.**

**Ask your health professional for advice before taking any medicine if you are unsure.**

## **PROPER USE OF THIS MEDICATION**

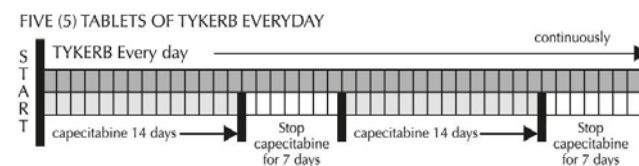
**Always take TYKERB exactly as your doctor has told you.** You should check with your doctor if you are not sure.

### **Usual dose:**

#### **TYKERB/capecitabine Combination**

Five TYKERB tablets (a total dose of 1250 mg) once daily continuously in combination with capecitabine.

If you are prescribed TYKERB in combination with capecitabine, your doctor will advise you of the dose of capecitabine and when to take it. TYKERB AND CAPECITABINE TABLETS ARE SIMILAR IN COLOUR AND SIZE. THEREFORE, IT IS VERY IMPORTANT THAT YOU LOOK CLOSELY AT YOUR TABLETS AND IDENTIFY THEM CORRECTLY BEFORE YOU TAKE THEM TO AVOID CONFUSION. Refer also to "**What dosage forms it comes in**" above.



#### **TYKERB/letrozole Combination**

Six TYKERB tablets (a total dose of 1500 mg) once daily continuously with letrozole.

If you are prescribed TYKERB in combination with letrozole, your doctor will advise you about the dose of letrozole, when to take it and how often.

### **How to take:**

Swallow the tablets whole with water. TYKERB should be taken at least one hour before or at least

one hour after a low fat meal.  
 TYKERB tablets should be taken at about the same time each day.  
 Do not drink grapefruit juice while you are taking TYKERB.

If you have any problems/questions regarding the use of TYKERB, please consult with your health professional.

**Overdose:**

Dosage directions should be followed carefully. Never exceed the prescribed dose.

If you have accidentally taken more TYKERB tablets than you should, contact your doctor, or poison control centre, or go to the emergency room of the nearest hospital.

**Missed Dose:**

**Do not** take a double dose to make up for a forgotten dose on a given day, simply resume your dosing with the next scheduled dose the following day. If you have further questions on the use of TYKERB, ask your health professional.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, TYKERB can cause side effects. Most of the side effects are mild to moderate. **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or bothers you**, or if you notice any side effects not listed in this leaflet.

Side effects of TYKERB in combination with capecitabine (XELODA<sup>®</sup>) or letrozole (FEMARA<sup>®</sup>) include:

**Very common side effects:**

*These side effects may affect more than 10 in every 100 patients.*

- Diarrhea (which if severe can be life-threatening), contact your doctor immediately at the first sign of diarrhea (loose stool), to treat it right away. Also tell your doctor immediately if your diarrhea worsens.
- Loss of appetite
- Indigestion or stomach/abdominal pain
- Feeling or being sick (nausea or vomiting)
- Constipation
- Tiredness
- Unusual hair loss or thinning
- Nose bleed
- Difficulty breathing
- Sore mouth or mouth ulcers
- Trouble sleeping (insomnia)
- Back pain or pain in extremities

- Rash or dry skin
- A skin reaction or pain on the palms of the hands or soles of the feet (including tingling, numbness, pain, swelling or reddening)

Supportive skin care regimens are available. Please talk to your healthcare provider for guidance.

**Common side effects:**

*These side effects may affect between 1 to 10 in every 100 people.*

- An effect on how your heart works – this may cause an irregular heartbeat and shortness of breath
- Headache
- Fever
- Swelling in extremities
- Pain in joints or bones
- Nosebleed
- Nail disorders – such as tender infection and swelling of the cuticles

If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations, fainting, or seizures, **you should seek immediate medical attention.**

**Uncommon side effects:**

*These side effects may affect up to 1 in every 100 people.*

- Liver problems – this may cause itching, yellow eyes or skin (jaundice), dark urine or pain or discomfort in the right upper area of the stomach.
- Swelling or inflammation of the lungs – this may cause coughing or shortness of breath.

**Tell your doctor immediately if you get any of these symptoms.** These symptoms may persist after you stop taking TYKERB.

**Rare side effects:**

*These side effects may affect up to 1 in every 1000 people.*

- Severe allergic reactions – symptoms may include: skin rash (including itchy, bumpy rash); unusual wheezing or difficulty in breathing; swollen eyelids, lips or tongue; pains in muscles or joints; collapse or blackout.

**Tell your doctor immediately if you get any of these symptoms and do not take any more tablets.**

**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	
Very Common	diarrhea		✓	
Common	Heart problems, which may cause: irregular heartbeat shortness of breath		✓	✓
Uncommon	Liver problems Lung inflammation (interstitial lung disease)		✓ ✓	
Rare	Severe allergic reactions			✓
Unknown	Severe skin reactions (symptoms may include blistering of the lips, eyes or mouth, skin peeling, fever or any combination of these)			✓

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

**HOW TO STORE IT**

- Store between 15-30°C.
- Keep out of the reach and sight of children.

**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 at [www.healthcanada.gc.ca/medeffect](http://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, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
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](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. 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 at: <http://www.novartis.ca> or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc. 385 Bouchard Blvd., Dorval, Quebec H9S 1A9 1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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