

## **PATIENT INFORMATION**

### **TYKERB® (TIE-curb) (lapatinib) tablets**

Read this leaflet before you start taking TYKERB and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

#### **What is TYKERB?**

TYKERB is used with the medicine capecitabine for the treatment of people with advanced or metastatic breast cancer that is HER2-positive (tumors that produce large amounts of a protein called human epidermal growth factor receptor-2), and who have already had certain other breast cancer treatments.

TYKERB is also used with a type of medicine called letrozole for the treatment of postmenopausal women with hormone receptor-positive, HER2-positive metastatic breast cancer for whom hormonal therapy is indicated.

It is not known if TYKERB is safe and effective in children.

#### **Who should not take TYKERB?**

Do not take TYKERB if you are allergic to any of the ingredients in TYKERB. See the end of this leaflet for a complete list of ingredients in TYKERB.

#### **What should I tell my doctor before taking TYKERB?**

**Before you take TYKERB,** tell your doctor if you:

- have heart problems.
- have liver problems. You may need a lower dose of TYKERB.
- have any other medical conditions.
- are pregnant or plan to become pregnant. TYKERB can harm your unborn baby. You should not become pregnant while taking TYKERB. Tell your doctor right away if you become pregnant during treatment with TYKERB.
- are breastfeeding or plan to breastfeed. It is not known if TYKERB passes into your breast milk. You and your doctor should decide if you will take TYKERB or breastfeed. You should not do both.

**Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. TYKERB may affect the way other medicines work, and other medicines may affect the way TYKERB works.

Especially tell your doctor if you take:

- antibiotics and antifungal medicines (used to treat infections)
- HIV medicines
- medicines used to treat seizures
- medicines used to treat heart problems or high blood pressure

- antidepressants
- medicines that reduce stomach acid (antacids)
- St. John's wort

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine. Do not take other medicines during treatment with TYKERB without first talking with your doctor.

### **How should I take TYKERB?**

- Take TYKERB exactly as your doctor tells you to take it. Your doctor may change your dose of TYKERB if needed.
  - For people with advanced or metastatic breast cancer, TYKERB and capecitabine are taken in 21-day cycles. The usual dose of TYKERB is 1,250 mg (5 tablets) taken by mouth all at once, **one time a day on days 1 to 21**.
  - Your doctor will tell you the dose of capecitabine you should take and when you should take it.
  - Take capecitabine with food or within 30 minutes after food.
  - For people with hormone receptor-positive, HER2-positive breast cancer, TYKERB and letrozole are taken **every day**. The usual dose of TYKERB is 1,500 mg (6 tablets) taken by mouth all at once, **one time a day**. Your doctor will tell you the dose of letrozole you should take and when you should take it.
- TYKERB should be taken at least 1 hour before, or at least 1 hour after a meal.
- Do not eat or drink grapefruit products during treatment with TYKERB.
- If you miss a dose of TYKERB, take your next dose at your regular time the next day.
- If you take too much TYKERB, call your doctor or go to the nearest hospital emergency room right away.

### **What are the possible side effects of TYKERB?**

**TYKERB may cause serious side effects**, including:

- **heart problems**, including decreased pumping of blood from the heart and an abnormal heartbeat. Signs and symptoms of an abnormal heartbeat include:
  - feeling like your heart is pounding or racing
  - dizziness
  - tiredness
  - feeling lightheaded
  - shortness of breath

Your doctor should check your heart function before you start taking TYKERB and during treatment.

- **liver problems**. Liver problems can be severe and deaths have happened. Signs and symptoms of liver problems include:
  - itching
  - yellowing of your skin or the white part of your eyes
  - dark urine
  - pain or discomfort in the right upper stomach area

Your doctor should do blood tests to check your liver before you start taking TYKERB and during treatment.

- **diarrhea.** Diarrhea is common with TYKERB and may sometimes be severe. Severe diarrhea can cause loss of body fluid (dehydration) and some deaths have happened. Call your doctor right away if you have a change in bowel pattern or if you have severe diarrhea. Follow your doctor's instructions for what to do to help prevent or treat diarrhea.
- **lung problems.** Symptoms of a lung problem with TYKERB include a cough that will not go away or shortness of breath.
- **severe skin reactions.** TYKERB may cause severe skin reactions. Tell your doctor right away if you develop a skin rash, red skin, blistering of the lips, eyes, or mouth, peeling of the skin, fever, or any combination of these. As severe skin reactions can be life-threatening, your doctor may tell you to stop taking TYKERB.

**Call your doctor right away if you have any of the signs or symptoms of the serious side effects listed above.**

**Common side effects** of TYKERB in combination with capecitabine or letrozole include:

- diarrhea
- red, painful hands and feet
- nausea
- rash
- vomiting
- tiredness or weakness
- mouth sores
- loss of appetite
- indigestion
- unusual hair loss or thinning
- nose bleeds
- headache
- dry skin
- itching
- nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of TYKERB. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**You may also get side effects from the other medicines taken with TYKERB.** Talk to your doctor about possible side effects you may get during treatment.

#### **How should I store TYKERB Tablets?**

- Store TYKERB Tablets at room temperature between 68° and 77°F (20° and 25°C).
- Keep the container closed tightly.
- Do not keep medicine that is out of date or that you no longer need.

**Keep TYKERB and all medicines out of the reach of children.**

## **General information about TYKERB**

Medicines are sometimes prescribed for purposes other than those listed in patient information leaflets. Do not use TYKERB for a condition for which it was not prescribed. Do not give TYKERB to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about TYKERB. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about TYKERB that is written for health professionals.

For more information, call 1-888-669-6682 or go to [www.tykerb.com](http://www.tykerb.com).

## **What are the ingredients in TYKERB?**

**Active ingredient:** Lapatinib.

**Inactive ingredients: Tablet Core:** Magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate. **Coating:** Orange film-coat: FD&C yellow No. 6/sunset yellow FCF aluminum lake, hypromellose, macrogol/PEG 400, polysorbate 80, titanium dioxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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