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404 **PATIENT INFORMATION**

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406 **TYKERB (TIE-curb)**  
407 **(lapatinib) tablets**  
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409 Read this leaflet before you start taking TYKERB<sup>®</sup> and each time you get a refill. There may be  
410 new information. This information does not take the place of talking with your doctor about your  
411 medical condition or treatment.

412  
413 **What is TYKERB?**

414 TYKERB is used with the medicine capecitabine for the treatment of patients with advanced or  
415 metastatic breast cancer that is HER2 positive, and who have already had certain other breast  
416 cancer treatments.

417  
418 **Before you start taking TYKERB, tell your doctor about all of your medical conditions,**  
419 **including if you:**

- 420 • have heart problems.
- 421 • **have liver problems. You may need a lower dose of TYKERB.**
- 422 • are pregnant or may become pregnant. TYKERB may harm an unborn baby. If you become  
423 pregnant during treatment with TYKERB, tell your doctor as soon as possible.
- 424 • are breastfeeding. It is not known if TYKERB passes into your breast milk or if it can harm  
425 your baby. If you are a woman who has or will have a baby, talk with your doctor about the  
426 best way to feed your baby.

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428 Tell your doctor about all the medicines you take, including prescription and nonprescription  
429 medicines and herbal and dietary supplements. TYKERB and many other medicines may interact  
430 with each other. Your doctor needs to know what medicines you take so he or she can choose the  
431 right dose of TYKERB for you.

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433 Especially tell your doctor if you take:

- 434 • antibiotics and anti-fungals (drugs used to treat infections)
- 435 • HIV (AIDS) treatments
- 436 • anticonvulsant drugs (drugs used to treat seizures)
- 437 • calcium channel blockers (drugs used to treat certain heart disorders or high blood pressure)
- 438 • antidepressants
- 439 • drugs used for stomach ulcers
- 440 • St. John's Wort or other herbal supplements

441

442 Know the medicines you take. Keep a list of your medicines with you to show your doctor. Do  
443 not take other medicines during treatment with TYKERB without first checking with your  
444 doctor.

445

446 Because TYKERB is given with another drug called capecitabine, you should also discuss with  
447 your doctor or pharmacist any medicines that should be avoided when taking capecitabine.

448

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

- 450 • Take TYKERB exactly as your doctor has told you. TYKERB and capecitabine are taken in  
451 21 day cycles. The usual dose of TYKERB is 1,250 mg (5 tablets) taken by mouth, **one time**  
452 **a day on days 1 to 21**. Your doctor will tell you the dose of capecitabine you should take  
453 and when you should take it.
- 454 • TYKERB should be taken at least one hour before, or at least one hour after food.
- 455 • Do not eat or drink grapefruit products while taking TYKERB.
- 456 • Your doctor may adjust your dose of TYKERB depending on how you tolerate the  
457 treatment.
- 458 • If you forget to take your dose of TYKERB, take it as soon as you remember that day. If  
459 you miss a day, do not double your dose the next day. Just skip the missed dose.

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

##### 462 **Serious side effects include:**

- 463 • **heart problems**
  - 464 • decreased pumping of blood from the heart
  - 465 • abnormal heartbeat
- 466 • **liver problems, which may cause itching, yellow eyes or skin, dark urine, or pain or**  
467 **discomfort in the right upper area of the belly.**
- 468 • **Your doctor should do blood tests to check your liver before you start taking TYKERB**  
469 **and during treatment.**
- 470 • **lung problems**
- 471 • **severe diarrhea, which may lead to you becoming dehydrated**

472

473 **Call your doctor right away if you have palpitations, persistent cough, shortness of breath,**  
474 **or severe diarrhea.**

475

##### 476 **Common side effects of TYKERB in combination with capecitabine include:**

- 477 • diarrhea
- 478 • red, painful hands and feet
- 479 • nausea
- 480 • rash

- 481 • vomiting
- 482 • tiredness
- 483 • mouth sores
- 484 • loss of appetite
- 485 • indigestion

486

487 Tell your doctor about any side effect that gets serious or that does not go away.

488

489 These are not all the side effects with TYKERB. Ask your doctor or pharmacist for more  
490 information.

491

492 **You may also get side effects from capecitabine.** Talk to your doctor about possible side  
493 effects with capecitabine.

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#### 495 **How should I store TYKERB tablets?**

- 496 • Store TYKERB tablets at room temperature between 59° and 86°F (15° to 30°C). Keep the  
497 container closed tightly.
- 498 • Do not keep medicine that is out of date or that you no longer need. Be sure that if you  
499 throw any medicine away, it is out of the reach of children.
- 500 • **Keep TYKERB and all medicines out of the reach of children.**

501

#### 502 **General information about TYKERB**

503 Medicines are sometimes prescribed for conditions that are not mentioned in patient information  
504 leaflets. Do not use TYKERB for any other condition for which it was not prescribed. Do not  
505 give TYKERB to other people, even if they have the same condition that you have. It may harm  
506 them.

507

508 This leaflet summarizes the most important information about TYKERB. If you would like more  
509 information, talk with your doctor. You can ask your doctor or pharmacist for information about  
510 TYKERB that is written for health professionals. For more information you can call toll-free 1-  
511 888-825-5249.

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

514 **Active Ingredient:** Lapatinib.

515 **Inactive Ingredients: Tablet Core:** Magnesium stearate, microcrystalline cellulose, povidone,  
516 sodium starch glycolate. **Coating:** Orange film-coat: FD&C yellow #6/sunset yellow FCF  
517 aluminum lake, hypromellose, macrogol/PEG 400, polysorbate 80, titanium dioxide.

518

519 TYKERB tablets are oval, biconvex, orange, film-coated with GS XJG printed on one side.

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527 Research Triangle Park, NC 27709

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531 Revised: Month YEAR

532 TKB:XPIL

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