

TYKERB® (Lapatinib) Tablets FACT SHEET

What is Tykerb?

- A small molecule, dual inhibitor of EGFR (ErbB1) and HER2 (ErbB2) discovered and developed by GSK as an oral therapy approved by the FDA for use in combination with capecitabine.
- Tykerb is in a class of cancer treatments called targeted therapies, designed to interfere with discrete cellular processes or disease mechanisms prevalent in cancer.
- Tykerb (lapatinib), in combination with capecitabine, is approved by the FDA for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.

Tykerb Characteristics

- The first and only once daily oral treatment option of its kind for this patient population. As an oral therapy, Tykerb offers added convenience for patients.
- It is proposed to work by inhibiting two validated targets in oncology – the kinase components of the EGFR (ErbB1) and HER2 (ErbB2) receptors – commonly associated with cancer cell proliferation and tumor growth.

What clinical trials involve Tykerb?

- GSK has a comprehensive clinical program that is actively studying Tykerb in other breast cancer settings, as well as other cancers to better identify patient populations that may respond to Tykerb.
- GSK has filed marketing applications for lapatinib around the world, including the EU, Switzerland, Canada, Brazil, Australia, and South Korea.

Important Safety Information*

As with other therapies for HER2 overexpression, TYKERB has been associated with reports of decreases in left ventricular ejection fraction (LVEF). Caution should be taken if TYKERB is to be administered to patients with preexisting cardiac conditions, including uncontrolled or symptomatic angina, arrhythmias, or congestive heart failure. LVEF should be evaluated in all patients prior to and during treatment with TYKERB.

Caution should be taken if TYKERB is to be administered to patients with severe hepatic impairment due to increased systemic exposure to the drug.

TYKERB prolongs the QT interval in some patients. Consider ECG and electrolyte monitoring.

Diarrhea, including severe diarrhea, has been reported during treatment with TYKERB. Proactive management of diarrhea with antidiarrheal agents is important, and severe cases of diarrhea may require administration of oral or intravenous electrolytes and fluids and interruption or discontinuation of therapy with TYKERB.

Fetal harm can occur when administered to a pregnant woman. Woman should be advised not to become pregnant when taking TYKERB.

The most common adverse events during treatment with TYKERB plus capecitabine were diarrhea, hand-foot syndrome, nausea, rash, vomiting and fatigue.

*Please see full prescribing information