

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Tykerb®
<b>Generic Name</b>	lapatinib
<b>Drug Manufacturer</b>	Natco Pharma Limited

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First Time Generic Approval

#### FDA APPROVAL DATE

September 29, 2020

#### LAUNCH DATE

September 29, 2020 (FDB addition date)

#### REVIEW DESIGNATION

N/A

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA)-203007

#### DISPENSING RESTRICTIONS

None

### Overview

#### INDICATION FOR USE

Tykerb® is a kinase inhibitor indicated in combination with:

- capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress human epidermal growth factor receptor 2 (HER2) and who have received prior therapy including an anthracycline, ataxane, and trastuzumab.
  - Limitations of Use: Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb® in combination with capecitabine.
- letrozole for the treatment of postmenopausal women with hormone receptor-positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.

#### MECHANISMS OF ACTION

Lapatinib is a 4-anilinoquinazoline kinase inhibitor of the intracellular tyrosine kinase domains of both Epidermal Growth Factor Receptor (EGFR [ErbB1]) and of Human Epidermal Receptor Type 2 (HER2 [ErbB2]) receptors (estimated Kiapp values of 3nM and 13nM, respectively) with a dissociation half-life of greater than or equal to 300 minutes. Lapatinib inhibits ErbB-driven tumor cell growth in vitro and in various animal models.

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### DOSE FORM AND STRENGTH

Tablet 250 mg (Base)

### DOSE & ADMINISTRATION

**Breast cancer, advanced or metastatic, HER2 overexpression, in combination with capecitabine after prior therapies:**

- 1250 mg (5 tablets) orally once daily continuously (days 1 through 21) in combination with capecitabine 2000 mg/m<sup>2</sup>/day orally (divided into 2 doses every 12 hours) on days 1 through 14 in a repeating 21-day cycle until treatment progression or unacceptable toxicity.

**Breast cancer, Postmenopausal women, hormone receptor-positive, HER2 overexpression, in combination with letrozole:**

- 1500 mg (6 tablets) orally once daily continuously in combination with letrozole 2.5 mg orally once daily.

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