RXADVANCE
2 Park Central Drive
Southborough, MA 01772

FIRST TIME GENERIC APPROVAL

Brand Name	Tykerb®
Generic Name	lapatinib
Drug Manufacturer	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(2)/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.