

## ABOUT NERLYNX<sup>®</sup> (NERATINIB) TABLETS<sup>1</sup>



### What is NERLYNX (ner links)?

NERLYNX is the first HER2-targeted medication approved by the U.S. Food and Drug Administration (FDA) as extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer, which means that it's designed to be taken by patients who have previously been treated with the medicine Herceptin<sup>®</sup> following surgery (i.e., adjuvant trastuzumab-based therapy).



### What is extended adjuvant therapy?

Extended adjuvant therapy is the next step of treatment that follows adjuvant therapy (treatment after surgery) to further reduce the risk of breast cancer returning.



### How does NERLYNX work?

NERLYNX is a tablet taken by mouth. It targets multiple HER family receptors and works inside the cell to block multiple growth pathways.



### Who is eligible to take NERLYNX?

In the United States, physicians can prescribe NERLYNX for patients with early-stage HER2+ breast cancer who have received prior trastuzumab-based treatment (adjuvant therapy).



### Do patients need to be re-tested for HER2 before they receive NERLYNX?

No, but patients must have received prior adjuvant (following surgery) trastuzumab-based therapy (Herceptin<sup>®</sup>). Your healthcare provider should do a pregnancy test as NERLYNX can cause harm to your unborn baby. Effective birth control is recommended.



### How effective is NERLYNX?

NERLYNX has been extensively studied in more than 3,000 patients,<sup>2</sup> including in the ExteNET trial. ExteNET evaluated treatment with NERLYNX after adjuvant trastuzumab-based therapy in 1,420 women with early-stage HER2+ breast cancer. In this study, NERLYNX reduced the risk of recurrence\* by 34% vs. placebo at two years. NERLYNX was also evaluated in an exploratory analysis at five years, which suggested results similar to those seen at two years.



### Is NERLYNX safe?

Common side effects of NERLYNX include diarrhea, nausea, stomach-area (abdomen) pain, tiredness, vomiting, rash, dry or inflamed mouth, or mouth sores, decreased appetite, muscle spasms, upset stomach, nail problems including color change, dry skin, swelling of your stomach area, weight loss and urinary tract infection. While diarrhea is a common side effect while taking NERLYNX, it can also be severe. Taking the anti-diarrhea medicine loperamide can help limit this symptom when it is started with the first dose of NERLYNX and taken during the first two months (56 days) of treatment, and then as needed.



### How often do patients take NERLYNX and for how long?

The recommended dose of NERLYNX is 240 mg (six tablets, 40 mg each) taken by mouth once daily with food, continuously for one year.



### Is NERLYNX covered by insurance?

The Puma Patient Lynx<sup>™</sup> support program offers reimbursement counselors who can help with a benefits investigation, verify insurance approval or coverage and obtain and submit necessary documentation for patients requiring prior authorization. To learn more, visit [NERLYNX.com](http://NERLYNX.com) or call **1-855-816-5421**, Monday through Friday, 9:00 AM–8:00 PM Eastern Time, to connect with someone for more information. Please see the next page for additional program details.

\*Recurrence is defined as an invasive disease event or death.

### Select IMPORTANT SAFETY INFORMATION

Changes in liver function tests are common with NERLYNX. Your healthcare provider should do blood tests before you begin treatment, monthly during the first 3 months, and then every 3 months as needed during treatment with NERLYNX. Your healthcare provider will stop your treatment with NERLYNX if your liver tests show severe problems. Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems: tiredness, nausea, vomiting, pain in the right upper stomach-area (abdomen), fever, rash, itching, yellowing of your skin or whites of your eyes.

These are not all the possible side effects of NERLYNX. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For additional IMPORTANT SAFETY INFORMATION, please see [Patient Information](#).

## ABOUT HER2+ BREAST CANCER AND DISEASE RECURRENCE



### What is HER2+ breast cancer?

HER2 (Human Epidermal Growth Factor Receptor 2) is a type of protein found on the surface of everyone's cells. This protein tells cells how and when to grow and divide. HER2+ breast cancer cells, however, have more HER2 receptors than normal breast cells. Having more HER2 receptors causes tumor cells to grow and divide faster, which increases the risk of the cancer spreading outside of the breast.<sup>3</sup>



### What is the risk of disease recurrence in HER2+ breast cancer?

HER2+ breast cancer is very aggressive and although some treatments have improved outcomes for patients, they have not eliminated the risk of cancer returning in patients with early-stage HER2+ disease. Up to 1 in 4 early-stage HER2+ breast cancer patients experience recurrence\* after adjuvant therapy (following surgery).<sup>4-8</sup> The majority of disease recurrences involve cancer that has spread to other parts of the body (metastatic breast cancer).<sup>8</sup>

## PUMA PATIENT LYNX™ SUPPORT PROGRAM

### What services are available to support patients taking NERLYNX?



#### For patients prescribed NERLYNX, Puma Patient Lynx provides a number of support services:

- **Benefits verification and prior authorization assistance:** Reimbursement counselors will conduct a benefits investigation, verify insurance approval or coverage, and obtain and submit necessary documentation for patients requiring prior authorization
- **Financial support:** For patients with financial needs, Puma Patient Lynx will help find appropriate sources for support
- **Co-pay assistance:** Commercially insured, eligible patients treated with NERLYNX may pay as little as \$10 per prescription (limitations apply; contact the toll-free number below for full terms and conditions)
- **NERLYNX Quick Start:** This program provides a free three-week supply of NERLYNX to eligible patients who are experiencing delays in gaining access to the medication



#### For patients currently taking NERLYNX, Puma Patient Lynx provides the following services:

- **Product support:** The Puma Patient Lynx specialty pharmacy network will provide education and side effect counseling to help NERLYNX patients better understand and manage their therapy
- **Text message support program:** Patients can sign up to receive medication reminders and motivational messages to support treatment continuation

PumaPatientlynx™

To learn more about the Puma Patient Lynx support program, visit [NERLYNX.com](https://www.nerlynx.com) or call 1-855-816-5421, Monday through Friday, 9:00 AM–8:00 PM Eastern Time, to connect with someone for more information.

\*Recurrence is defined as an invasive disease event or death.

For IMPORTANT SAFETY INFORMATION, please see [Patient Information](#).

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1. NERLYNX (neratinib) tablets Prescribing Information, Puma Biotechnology, 07/17. 2. Puma Biotechnology, Inc., Data on File, 05/17. 3. National Comprehensive Cancer Network®. NCCN Guidelines for Patients®. Breast Cancer - Early-Stage (Stages I and II), Version 1.2016. Published online at <https://www.nccn.org/patients/>. 4. Perez EA, Romond EH, Suman VJ, et al. Trastuzumab plus adjuvant chemotherapy for human epidermal growth factor receptor 2-positive breast cancer: planned joint analysis of overall survival from NSABP B-31 and NCCTG N9831. *J Clin Oncol*. 2014;32(33):3744-3752. 5. Joensuu H, Bono P, Kataja V, et al. Fluorouracil, epirubicin, and cyclophosphamide with either docetaxel or vinorelbine, with or without trastuzumab, as adjuvant treatments of breast cancer: final results of the FinHer Trial. *J Clin Oncol*. 2009;27(34):5685-5692. 6. Goldhirsch A, Gelber RD, Piccart-Gebhart MJ, et al. 2 years versus 1 year of adjuvant trastuzumab for HER2-positive breast cancer (HERA): an open label, randomised controlled trial. *Lancet*. 2013;382(9897):1021-1028. 7. Slamon DJ, Eiermann W, Robert NJ, et al. Ten-year follow-up of BCIRG-006 comparing doxorubicin plus cyclophosphamide followed by docetaxel with doxorubicin plus cyclophosphamide followed by docetaxel and trastuzumab with docetaxel, carboplatin and trastuzumab in HER2-positive early breast cancer patients. Presented at: 2015 San Antonio Breast Cancer Symposium; December 11, 2015; San Antonio, TX. Abstract S5-04. 8. Cameron D, Piccart-Gebhart MJ, Gelber RD, et al. 11 years' follow-up of trastuzumab after adjuvant chemotherapy in HER2-positive early breast cancer: final analysis of the herceptin adjuvant (HERA) trial. *Lancet*. 2017;389(10075):1195-1205.

## PATIENT INFORMATION

### NERLYNX (ner links)

(neratinib)

tablets

#### What is the most important information I should know about NERLYNX?

##### NERLYNX may cause serious side effects, including:

- **Diarrhea.** Diarrhea is a common side effect of NERLYNX, but it can also be severe. You may lose too much body salts and fluids, and get dehydrated. Your healthcare provider should prescribe the medicine loperamide for you during your first 2 months (56 days) of NERLYNX and then as needed. To help prevent or reduce diarrhea:
  - You should start taking loperamide with your first dose of NERLYNX.
  - Keep taking loperamide during the first 2 months (56 days) of NERLYNX treatment and then as needed. Your healthcare provider will tell you exactly how much and how often to take loperamide.
  - Always take loperamide exactly as your healthcare provider tells you.
  - While taking loperamide, you and your healthcare provider should try to keep the number of bowel movements that you have at 1 or 2 bowel movements each day.
  - Tell your healthcare provider if you have more than 2 bowel movements in 1 day, or you have diarrhea that does not go away.
  - **Call your healthcare provider right away, as instructed, if you have severe diarrhea or if you have diarrhea along with weakness, dizziness, or fever.**
  - Your healthcare provider may also need to give you other medicines to manage diarrhea if loperamide does not work well enough.
  - After 2 months (56 days) of treatment with NERLYNX, follow your healthcare provider's instructions about taking loperamide as needed to control diarrhea.

Your healthcare provider may change your dose of NERLYNX, temporarily stop or completely stop NERLYNX if needed to manage your diarrhea.

See "**What are the possible side effects of NERLYNX?**" for more information about side effects.

#### What is NERLYNX?

NERLYNX is a prescription medicine used to treat adults who have early-stage breast cancer, which:

- is HER2-positive **and**
- has previously been treated with the medicine trastuzumab.

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

#### Before taking NERLYNX, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems. You may need a lower dose of NERLYNX.
- are pregnant or plan to become pregnant. NERLYNX can harm your unborn baby. If you are a female who can become pregnant:
  - Your healthcare provider should do a pregnancy test before you start taking NERLYNX.
  - You should use effective birth control (contraception) during treatment and for at least 1 month after your last dose of NERLYNX.
  - Talk with your healthcare provider about forms of birth control that you can use during this time.
  - Tell your healthcare provider right away if you become pregnant during treatment with NERLYNX.
  - Males with female partners who can become pregnant should use effective birth control during treatment and for 3 months after the last dose of NERLYNX.
- are breastfeeding or plan to breastfeed. It is not known if NERLYNX passes into your breast milk. Do not breastfeed during treatment and for at least 1 month after your last dose of NERLYNX.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take medicines used to decrease stomach acid, called proton pump inhibitors or PPIs, and H-2 receptor antagonists. You should avoid taking these medicines during treatment with NERLYNX.

### How should I take NERLYNX?

- Take NERLYNX exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose of NERLYNX if needed.
- Take NERLYNX with food.
- Take NERLYNX at about the same time each day.
- If you take an antacid medicine, take NERLYNX 3 hours after the antacid medicine.
- NERLYNX is usually taken for 1 year.
- If you miss a dose of NERLYNX, skip that dose and take your next dose at your regular scheduled time.
- If you take too much NERLYNX, call your healthcare provider right away or go to the nearest hospital emergency room.

### What should I avoid during treatment with NERLYNX?

You should avoid eating products that contain grapefruit during treatment with NERLYNX.

### What are the possible side effects of NERLYNX?

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

**See “What is the most important information I should know about NERLYNX?”**

- **Liver problems.** Changes in liver function tests are common with NERLYNX. Your healthcare provider should do blood tests before you begin treatment, monthly during the first 3 months, and then every 3 months as needed during treatment with NERLYNX. Your healthcare provider will stop your treatment with NERLYNX if your liver tests show severe problems. Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:
  - tiredness
  - nausea
  - vomiting
  - pain in the right upper stomach-area (abdomen)
  - fever
  - rash
  - itching
  - yellowing of your skin or whites of your eyes

**Common side effects** of NERLYNX include:

- diarrhea
- nausea
- stomach-area (abdomen) pain
- tiredness
- vomiting
- rash
- dry or inflamed mouth, or mouth sores
- decreased appetite
- muscle spasms
- upset stomach
- nail problems including color change
- dry skin
- swelling of your stomach-area
- weight loss
- urinary tract infection

These are not all the possible side effects of NERLYNX.

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

### How should I store NERLYNX?

- Store NERLYNX at room temperature between 68° to 77°F (20° to 25°C).

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

### General information about the safe and effective use of NERLYNX.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NERLYNX for a condition for which it was not prescribed. Do not give NERLYNX to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about NERLYNX that is written for health professionals.

### What are the ingredients in NERLYNX?

**Active ingredient:** neratinib

**Inactive ingredients:** Tablet Core: colloidal silicon dioxide, mannitol, microcrystalline cellulose, crospovidone, povidone, magnesium stearate & purified water. Coating: red film coat: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide red.

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For more information, go to [www.NERLYNX.com](http://www.NERLYNX.com) or call 1-844-637-5969.

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

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