



ABOUT EARLY-STAGE HER2+ BREAST CANCER AND DISEASE RECURRENCE

What is HER2+ breast cancer?

HER2+ (human epidermal growth factor receptor 2-positive) breast cancer is different from other types of breast cancer. It tends to be more aggressive, and its chance of returning or progressing is a reality—even after completing prescribed treatment with other regimens. In some breast cancers, cancer cells have a gene mutation that makes too much HER2 protein. This protein promotes the growth of cancer cells. Among women with breast cancer, approximately 20% have HER2+ breast cancer. HER2+ breast cancer can grow fast and has a high chance of coming back and spreading in the body.

What is the risk of recurrence in early-stage HER2+ breast cancer?

HER2+ breast cancer tends to be more 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 within 10 years after being treated with trastuzumab-based therapy (ie, Herceptin®). The majority of disease recurrences involve cancer that has spread to other parts of the body (metastatic breast cancer).



ABOUT NERLYNX

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+ breast cancer, which means that it's designed for early-stage HER2+ breast cancer patients who have previously been treated with trastuzumab-based therapy (ie, Herceptin).

Who is eligible to take NERLYNX?

NERLYNX may be an option for you if you're an adult with early-stage HER2+ breast cancer, and if you have previously been treated with trastuzumab-based therapy (ie, Herceptin).

How does NERLYNX work?

In people with breast cancer, cells receive signals that cause the cells to grow and divide. NERLYNX is a type of treatment called a targeted therapy that works inside the cell to block these signals that tell the cells to grow and divide. By blocking HER2, breast cancer cells do not grow and divide as rapidly.*

How effective is NERLYNX?

NERLYNX has been extensively studied in more than 4,000 patients, including in the ExteNET trial. ExteNET evaluated treatment with NERLYNX after adjuvant trastuzumab-based therapy in women with early-stage HER2+ breast cancer. In this clinical trial of 2,840 women, NERLYNX reduced the risk of cancer returning by 34% at 2 years for women studied with HER2+ breast cancer. The clinical trial also looked at a subset of women with HER2+ breast cancer who were also hormone receptor positive (HR+) and found there was a 42% reduction in the risk of recurrence at 5 years.^{†‡}

What are the most common side effects of NERLYNX?

The most common side effects of NERLYNX when used alone 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, nosebleed, weight loss, and urinary tract infection. If you have any questions about the side effects you may experience while taking NERLYNX, please talk to your doctor or healthcare team.

*NERLYNX targets HER2+ cancer cells, but may also affect healthy cells.

[†]These are relative benefits. In absolute numbers, 94.2% of all people studied who were HER2+ and took NERLYNX had no return of cancer after 2 years, compared to the 91.9% of people on a placebo who had no return of cancer. After 5 years, 90.8% of all people studied who were HER2+ and HR+ and took NERLYNX had no return of cancer, compared to the 85.7% of people on a placebo who had no return of cancer.

[‡]5-year data are based on an exploratory analysis of people who were HR+ and had completed a trastuzumab-based treatment 1 year or less prior to treatment with NERLYNX. Of this HER2+, HR+ population, 95% were also on endocrine therapy.

INDICATIONS AND USAGE

- NERLYNX is a prescription medicine used alone to treat adults with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer **and** who have previously been treated with trastuzumab-based therapy.

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

For additional IMPORTANT SAFETY INFORMATION, including [Patient Information](#), please see pages 4 through 6 of this PDF.



BEFORE TAKING NERLYNX

Do I need to be re-tested for HER2 before taking NERLYNX?

If you have already tested positive for HER2+ breast cancer, you should ask your healthcare team whether you need to be re-tested before taking NERLYNX. However, in order to receive NERLYNX, you must have had prior adjuvant treatment (after surgery) with trastuzumab-based therapy (ie, Herceptin).

What if I'm not HER2+? Can I still take NERLYNX?

NERLYNX is a treatment for HER2+ breast cancer patients only. Talk to your healthcare team about the treatment options that may be right for you.

What if I'm taking endocrine therapy?

NERLYNX is an oral medicine that works differently from other HER2 treatments and endocrine therapy. NERLYNX has been extensively studied in more than 4,000 patients, including in the ExteNET trial where 93% of HER2+, HR+ patients on NERLYNX were also taking endocrine therapy at the same time. If you have questions about your medication, such as how to take NERLYNX with your other medications, please speak with your healthcare team or pharmacist, who can best answer them.

Is NERLYNX covered by insurance?

NERLYNX is covered by many insurance providers. For questions about insurance, the Puma Patient Lynx™ support program has resources for you to explore. Please see the next page for additional program details.

Where can I get NERLYNX?

Your doctor can provide you with a prescription that is filled through a network of specialty pharmacies. If you have questions related to your specific situation, please speak with your healthcare team.



WHILE TAKING NERLYNX

How can I best manage side effects I may experience?

Like all cancer treatments, NERLYNX may cause side effects. There are ways to manage the potential side effects of NERLYNX, so don't feel discouraged. Talk to your doctor or nurse about how to manage side effects. Your doctor can prescribe medication, recommend over-the-counter medicines, or reduce your dose of NERLYNX to help. Your doctor may also start you on a lower dose to help manage any anticipated side effects.

Diarrhea is the most common side effect that occurs, mainly in the first month.

Your doctor may advise you to take the antidiarrheal medicine loperamide (eg, Imodium[®]), which can help limit this symptom when it is started with the first dose of NERLYNX and taken during the first 2 months (56 days) of treatment, and then as needed.

How do I take NERLYNX and for how long?

The recommended dose of NERLYNX is 240 mg (6 tablets, 40 mg each) taken by mouth once daily from home with food, continuously for one year.

What if I miss a dose of NERLYNX?

If you miss a dose of NERLYNX, skip that dose and take your next dose at your regular scheduled time. If you have questions related to your specific situation, please speak with your healthcare team.

SELECT IMPORTANT SAFETY INFORMATION

What is the most important information I should know about NERLYNX (ner links)?

NERLYNX[®] (neratinib) 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 fluid, and get dehydrated. When you start NERLYNX, your healthcare provider should prescribe the medicine loperamide for you during your first 2 months (56 days) of NERLYNX and then as needed. Be sure that your healthcare provider prescribes anti-diarrheals with NERLYNX. Anti-diarrheals must be started with the first dose of NERLYNX.

For additional IMPORTANT SAFETY INFORMATION, including [Patient Information](#), please see pages 4 through 6 of this PDF.



PUMA PATIENT LYNX™ SUPPORT PROGRAM

What services are available to support patients interested in or currently taking NERLYNX?

Puma Patient Lynx programs and services provide ongoing education, encouragement, and financial assistance:

Ongoing Support

NERLYNX Mentor Program: When you start taking NERLYNX, the mentor program connects you with someone who currently takes or has taken NERLYNX.

Nurse Support: Nurses are available, Monday through Friday, 9 AM – 8 PM EST, to answer your NERLYNX questions through the call center.

Text Support Program: Receive guidance and reassurance through emails and texts that will help you stay committed to taking NERLYNX, remember to take your daily medicine, manage side effects, reduce stress and anxiety, and get the most out of your healthcare appointments

Access Programs

NERLYNX Quick Start: Provides a 3-week supply of NERLYNX to eligible patients whose access to medicine is delayed.

Patient Assistance Programs: For information or assistance with pharmacy insurance benefits, call 1-855-816-5421.

Co-pay Support: Commercially insured, eligible patients treated with NERLYNX may pay as little as \$10 per prescription.[§]

Supportive Care Voucher: Patients can receive up to a 3-month supply of products used for antidiarrheal treatment for free.^{||}

Specialty Pharmacy Services: NERLYNX is available through specialty pharmacies that help with much more than filling your prescription. They provide insurance verification, help with prior authorization requirements for insurance, on-time delivery of NERLYNX, nurses, and pharmacist counselors to help with questions about NERLYNX and side effects.

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 EST, to connect with someone for more information.

YOU CAN ALSO LEARN MORE ABOUT NERLYNX
BY CONNECTING WITH US



[§]Limitations apply. Patient must have commercial insurance. Offer is not valid under Medicare, Medicaid, or any other federal or state program. Puma Biotechnology reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, call 1-855-816-5421.

^{||}This program benefit is offered based on the findings from the CONTROL trial, which show that using antidiarrheals can help to manage diarrhea that may be caused by NERLYNX. Limitations apply. Puma Biotechnology reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, visit www.nerlynx.com or call 1-855-816-5421.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about NERLYNX (ner links)?

NERLYNX® (neratinib) 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 fluid, and get dehydrated. When you start NERLYNX, your healthcare provider should prescribe the medicine loperamide for you during your first 2 months (56 days) of NERLYNX and then as needed. Be sure that your healthcare provider prescribes anti-diarrheals with NERLYNX. Anti-diarrheals must be started with the first dose of NERLYNX. 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 this medicine.
 - Your healthcare provider may also need to give you other medicines to manage diarrhea when you start treatment with NERLYNX. Follow your healthcare provider's instructions on how to use these anti-diarrheal medicines.
 - Always take anti-diarrheals exactly as your healthcare provider tells you.
 - While taking anti-diarrheals, 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.**
 - 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 alone to treat adults with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer **and** who have previously been treated with trastuzumab-based therapy.

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 your 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. You should avoid taking these medicines 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

The most common side effects of NERLYNX when used alone 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
- nosebleed
- weight loss
- urinary tract infection

These are not all of the possible side effects of NERLYNX. For more information, ask your Healthcare Provider.

Tell your doctor if you have any side-effect that bother you or that does not go away. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For [Patient Information](#), please see pages 5 and 6 of this PDF.



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nerlynx[®]
(neratinib) tablets

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 fluid, and get dehydrated. When you start NERLYNX, your healthcare provider should prescribe the medicine loperamide for you during your first 2 months (56 days) of NERLYNX and then as needed. Be sure that your healthcare provider prescribes anti-diarrheals with NERLYNX. Anti-diarrheals must be started with the first dose of NERLYNX. 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 this medicine.
 - Your healthcare provider may also need to give you other medicines to manage diarrhea when you start treatment with NERLYNX. Follow your healthcare provider's instructions on how to use these anti-diarrheal medicines.
 - Always take anti-diarrheals exactly as your healthcare provider tells you.
 - While taking anti-diarrheals, 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.**
 - 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 alone to treat adults with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer **and** who have previously been treated with trastuzumab-based therapy.
- NERLYNX is also used with a medicine called capecitabine to treat adults with HER2-positive breast cancer that has spread to other parts of the body (metastatic) **and** who have received 2 or more anti-HER2 therapy medicines for metastatic breast cancer.

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. 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.
- Swallow NERLYNX tablets whole. Do not chew, crush, or split NERLYNX tablets.
- If you take an antacid medicine, take NERLYNX 3 hours after the antacid medicine.
- If you take an acid reducer (H₂ receptor blocker), NERLYNX should be taken at least 2 hours before or 10 hours after you take these medicines.
- 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 while taking 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:

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|--|---|
| ○ tiredness | ○ fever |
| ○ nausea | ○ rash |
| ○ vomiting | ○ itching |
| ○ pain in the right upper stomach-area (abdomen) | ○ yellowing of your skin or whites of your eyes |

The most common side effects of NERLYNX when used alone include:

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

The most common side effects of NERLYNX when used with capecitabine include:

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|----------------------|-------------------------------------|
| • diarrhea | • back pain |
| • nausea | • joint pain |
| • vomiting | • urinary tract infection |
| • decreased appetite | • upper respiratory tract infection |
| • constipation | • swelling of your stomach-area |
| • tiredness/weakness | • kidney problems |
| • weight loss | • muscle spasms |
| • dizziness | |

These are not all of the possible side effects of NERLYNX. For more information, ask your healthcare provider. Tell your doctor if you have any side effects that bother you or that does not go away. 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°F to 77°F (20°C 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, and purified water. Coating: red film coat: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and iron oxide red.

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