



I'm doing everything
in my power
**SO I CAN KEEP
DOING WHAT I LOVE.**

NERLYNX for
HER2+ breast cancer

Not an actual patient.

INDICATIONS AND USAGE

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.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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A woman with dark hair and a focused expression is painting on a canvas mounted on an easel. She is wearing a light-colored, patterned blouse and a beaded necklace. In the foreground, a blurred container holds various paintbrushes and tubes of paint in green, red, and white. The background is a soft, out-of-focus indoor setting.

POWER BEGINS WITH **KNOWLEDGE**

“ Being thrust into the cancer world is like learning a new language. I didn’t know there were different types of breast cancer. ”

- patient diagnosed with HER2+ breast cancer

Not an actual patient.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying Patient Information.

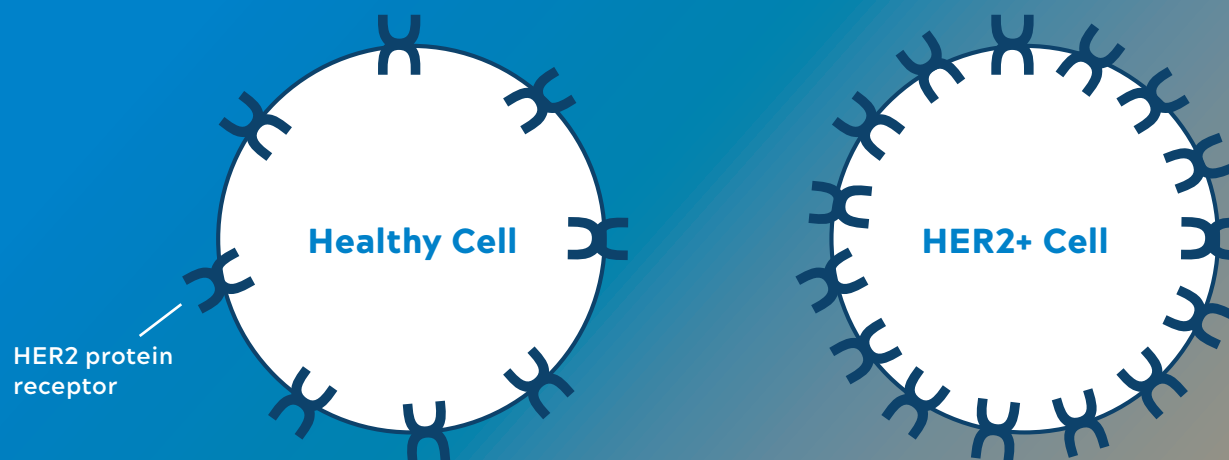
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WHAT IS HER2+ BREAST CANCER?

Some people with breast cancer have a gene mutation that causes their cells to make too much of the HER2 (human epidermal growth factor receptor 2) protein. At higher than normal levels, HER2 protein promotes the growth of abnormal cells, causing HER2+ breast cancer.

Among people with breast cancer, about 20%—or about 1 in 5—have HER2+ breast cancer. HER2+ breast cancer is different from other types of breast cancer. It tends to be more aggressive and grows quickly. It also has an increased chance of coming back or spreading, even after treatment with other regimens.

Until there is a cure for breast cancer, there is still a risk of the cancer returning or progressing. However, treatments for breast cancer are constantly advancing.



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WHAT IS EARLY-STAGE HER2+ BREAST CANCER?

As with most cancers, breast cancer is defined by stages. Early-stage breast cancer is cancer that has not spread beyond the breast or the lymph nodes under the arm.

Early-stage HER2+ breast cancer is highly treatable. But its chance of returning is still a reality, even after chemotherapy, surgery, and trastuzumab-based treatment (for example, Herceptin®). The risk of recurrence in women with early-stage HER2+ breast cancer can be as high as 30% within 10 years. Additional treatment taken after trastuzumab-based treatment—known as extended adjuvant therapy—may help you do more to further reduce that risk.

For people who have had neoadjuvant therapy, after surgery, your doctor will check to see if residual cancer cells remain in your breast tissue or nearby lymph nodes. If any cancer cells remain, this is referred to as not having a pathologic complete response, or no pCR. This result is one of many factors that will help determine your extended adjuvant treatment plan.

Each person has unique risk factors that affect the chance of their cancer returning. These include:

- **Characteristics of the cancer, such as the tumor size or lymph node involvement**
- **Age**
- **Overall health**

Talk to your doctor about including NERLYNX® (neratinib) in your treatment plan so you can do everything possible to increase your chance of reducing recurrence and staying cancer free longer.

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WHAT IS METASTATIC BREAST CANCER?

Metastatic breast cancer—also called Stage IV or advanced breast cancer—is cancer that has spread beyond the breast and nearby lymph nodes to other parts of the body.

In nearly 1 in 4 people (25%) with breast cancer diagnosed at an early stage, the cancer will come back as advanced, or metastatic, breast cancer. In 6% to 10% of new breast cancer cases, the cancer is metastatic from the start. This is called "de novo" metastatic breast cancer.

Treatment can control metastatic breast cancer for some time, but often the cancer continues to grow, or spread. A person's experience with metastatic breast cancer will depend on how many metastases develop and where they are in the body.

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THE POWER OF A **TARGETED TREATMENT**^a

Not an actual patient.

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.

^aNERLYNX targets HER2+ cancer cells, but may also affect healthy cells.

Please see additional **IMPORTANT SAFETY INFORMATION** throughout this brochure and the accompanying [Patient Information](#).

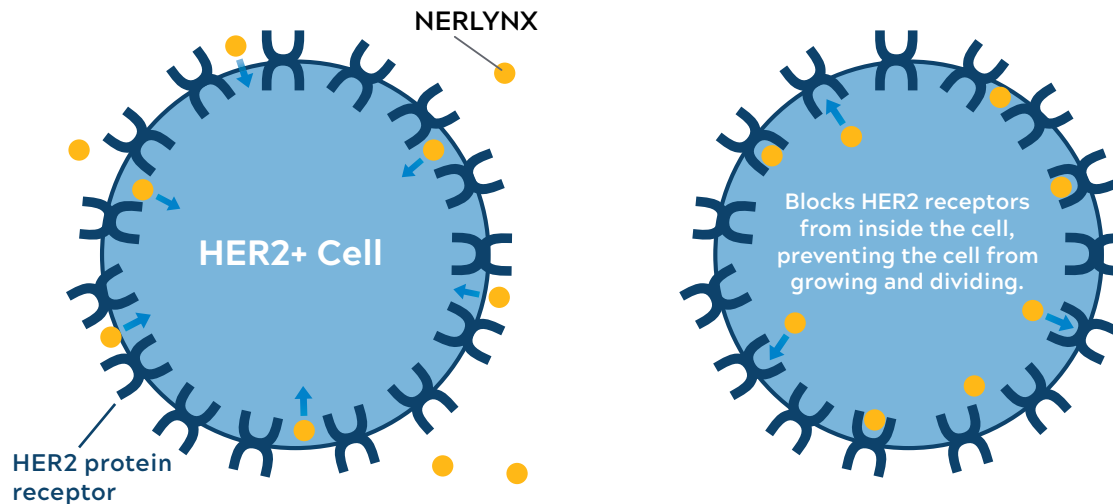
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WHAT IS NERLYNX?

People with HER2+ breast cancer have a gene that causes them to have too much HER2 protein in their cells. HER2 protein signals cells to grow and divide. But when too much of this protein is present, cells grow more aggressively than normal. NERLYNX® (neratinib) is a small-molecule, targeted therapy that enters the cell and works *inside* the cell to permanently stop this signal.

Some other treatments work *outside* the cell, blocking cancer cells from receiving the HER2 growth signals. But this blockade is only temporary while on treatment.

NERLYNX was also shown in a cell model to cross the blood-brain barrier. Up to 50% of women with HER2+ breast cancer will eventually have a recurrence in the brain.



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THE POWER TO **PREVENT RECURRENCE** WITH NERLYNX

In a clinical trial of women with HER2+ breast cancer, NERLYNX reduced the risk of recurrence by 34% at 2 years. Recurrence is defined as the cancer coming back or resulting in death.

Not an actual patient.

SELECT IMPORTANT SAFETY INFORMATION

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.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

What are the possible 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.

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WHAT ARE THE BENEFITS OF NERLYNX?

Since you were diagnosed with early-stage HER2+ breast cancer, you've no doubt faced many important decisions about your treatment.

NERLYNX® (neratinib) was studied in a clinical trial of 2,840 women who had early-stage HER2+ breast cancer. The majority of these women (81%) were enrolled within 1 year of completing trastuzumab-based treatment. The phase 3 trial examined the safety and effectiveness of NERLYNX by comparing women who took NERLYNX with those who were given a placebo.

These women were followed over time—some for as long as approximately 8 years. During that time, the investigators also looked at a subset of women with HER2+ breast cancer who were also HR+ (hormone receptor positive), had initiated NERLYNX within 1 year of completing trastuzumab-based treatment, and had residual disease (no pCR) at the time of surgery.

Participants were randomly selected to receive NERLYNX and were not told whether they were receiving the medicine or a placebo.

By committing to NERLYNX, you can be confident in knowing you are doing everything you can to lower your risk of your cancer coming back.

SELECT IMPORTANT SAFETY INFORMATION

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

- 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.

Please see additional **IMPORTANT SAFETY INFORMATION** throughout this brochure and the accompanying [Patient Information](#).

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In the clinical trial, NERLYNX reduced the risk of cancer returning by 34% at 2 years for all women studied with HER2+ breast cancer.^b

34%
REDUCTION^b

The clinical trial also looked at a subset of women with HER2+ breast cancer who were also HR+ and found there was a 42% reduction in the risk of recurrence at 5 years.^{c,d}

42%
REDUCTION FOR
HER2+ AND HR+^{c,d}

In a further subset of women who were HER2+ and HR+ and had residual disease after surgery (no pCR), the clinical trial found there was a 40% reduction in the risk of recurrence at 5 years.^{c,e}

40%
REDUCTION FOR
HER2+ AND HR+
WITH RESIDUAL
DISEASE^{c,e}

^bIn 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 placebo—a difference of 2.3%.

^c5-year data are based on an exploratory analysis that included 75% of patients enrolled (2,117 out of 2,840) who agreed to remain in the study beyond the initial 2 years. This analysis looked at multiple subsets of patients who had completed a trastuzumab-based treatment 1 year or less prior to treatment with NERLYNX. Of the HER2+ and HR+ population, 95% were also on endocrine therapy.

^dAfter 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 placebo—a difference of 5.1%.

^eIn absolute numbers, 85.0% of all people studied who were HER2+ and HR+, had residual disease (no pCR), and took NERLYNX had no return of cancer, compared to 77.6% of people on placebo—a difference of 7.4%.

SELECT IMPORTANT SAFETY INFORMATION

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

- To help prevent or reduce diarrhea (continued):
 - 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.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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NERLYNX EXTENDS SURVIVAL FOR SOME PATIENTS

At 8 years, an analysis of a subset of patients showed that NERLYNX[®] (neratinib) extended the length of survival in women with HER2+ and HR+ breast cancer and residual disease (no pCR).^c

At 5 years, overall survival was 94.1% for those taking NERLYNX compared to 93.3% for those given placebo. After 8 years of follow-up, there was no statistically significant difference in survival between NERLYNX and placebo.^c

In a subset of women who were HER2+ and HR+, the clinical trial found that there was a 21% reduction in the risk of death at 8 years.^{c,f}

21%
REDUCTION IN
THE RISK OF
DEATH FOR HER2+
AND HR+^{c,f}

In a further subset of women who were HER2+ and HR+ and had residual disease after surgery (no pCR), there was a 53% reduction in the risk of death at 8 years.^{c,g}

53%
REDUCTION
FOR HER2+
AND HR+ WITH
RESIDUAL DISEASE^{c,g}

^fThe absolute benefit of taking NERLYNX in overall survival at 8 years was 2.1% vs placebo in HER2+ and HR+ patients who had completed trastuzumab-based treatment 1 year or less prior to treatment with NERLYNX.

^gThe absolute benefit of taking NERLYNX in overall survival at 8 years was 9.1% vs placebo in HER2+ and HR+ patients who had residual disease and had completed trastuzumab-based treatment 1 year or less prior to treatment with NERLYNX.

SELECT IMPORTANT SAFETY INFORMATION

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

- To help prevent or reduce diarrhea:
 - 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.**

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

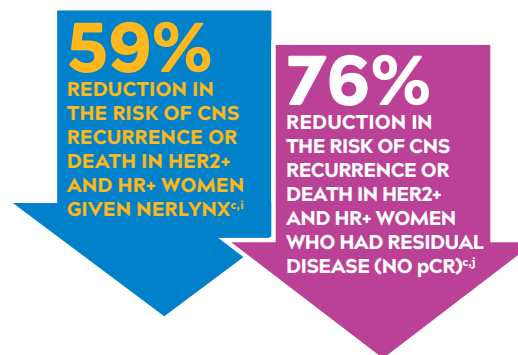
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(neratinib) tablets

PROTECTION AGAINST CNS METASTASES FOR SOME PATIENTS

In a descriptive analysis of a clinical trial, NERLYNX[®] (neratinib) was shown to protect against CNS (brain and spinal cord) metastases in women with early-stage breast cancer who had residual disease (no pCR). **At 5 years:**

In HER2+ and HR+ women given NERLYNX, 0.7% had their first recurrence (metastases) in the CNS, compared to 2.1% given placebo.^{c,h}

In a further subset of HER2+ and HR+ women who had residual disease (no pCR), 0.8% given NERLYNX had their first recurrence (metastases) in the CNS, compared to 3.6% given placebo.^{c,h}



^hIn HER2+ and HR+ women, the absolute difference was 1.4%. In HER2+ and HR+ women who had residual disease (no pCR) and who had completed trastuzumab-based treatment 1 year or less prior to treatment with NERLYNX, the absolute difference was 2.8%.

ⁱIn absolute numbers, 98.4% of those given NERLYNX (n=670) did not experience a CNS recurrence or death from any cause, compared to 95.7% of those given placebo (n=664)—a benefit of 2.7%.

^jIn absolute numbers, 98.4% of those given NERLYNX (n=131) did not experience a CNS recurrence or death from any cause, compared to 92.0% of those given placebo (n=164)—a benefit of 6.4%.

SELECT IMPORTANT SAFETY INFORMATION

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

- To help prevent or reduce diarrhea (continued):
 - 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.

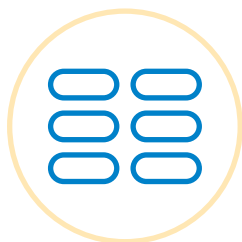
Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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(neratinib) tablets

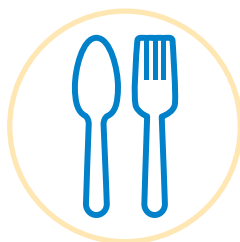
HOW TO TAKE NERLYNX

NERLYNX® (neratinib) is an oral medicine that you take once a day at home. NERLYNX should be taken soon after finishing a trastuzumab-based treatment for early-stage breast cancer. It takes 1 year to complete a full course of treatment for early-stage breast cancer to help reduce the risk of your cancer coming back.

Take 6 Tablets
40 mg Tablets



1x a Day
With Food



For 1 Year
Continuously
(or until the cancer returns)



With Antidiarrheal
For the First 2 Months
(or as prescribed)



- Never take more than 1 dose (6 tablets) per day.
- Do not chew, crush, or split tablets.
- Avoid eating products that contain grapefruit during treatment with NERLYNX.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

nerlynx®
(neratinib) tablets

NERLYNX DOSING

When you are prescribed NERLYNX® (neratinib) for early-stage breast cancer, your doctor may start you on a lower dose. Over time, your doctor will increase the dose until you are taking 6 tablets once a day. This can help you to adjust to NERLYNX by managing side effects so you can stay on treatment.

As with most medicines, side effects can occur with NERLYNX. Working with your healthcare team from the beginning is the key to success. Be sure to let your doctor know about any side effects you experience and ask for help to manage them.



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Not an actual patient.

THE POWER TO **REDUCE THE RISK OF PROGRESSION** WITH NERLYNX

In a clinical trial of 621 people with HER2+ metastatic breast cancer, NERLYNX, in combination with capecitabine (a chemotherapy), reduced the risk of cancer progressing by 24%.

SELECT IMPORTANT SAFETY INFORMATION

What is NERLYNX?

- 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.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

What are the possible side effects of NERLYNX?

The most common side effects of NERLYNX in combination with capecitabine include diarrhea, nausea, vomiting, decreased appetite, constipation, tiredness/weakness, weight loss, dizziness, back pain, joint pain, urinary tract infection, upper respiratory tract infection, swelling of your stomach-area, kidney problems, and muscle spasms.

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WHAT ARE THE BENEFITS OF NERLYNX?

When you are living with metastatic breast cancer, you likely face a number of decisions. One of the most important decisions you will make with your healthcare team is which treatment is right for you.

NERLYNX® (neratinib) was studied in a clinical trial of 621 people who had HER2+ metastatic breast cancer and had undergone treatment with 2 or more HER2-directed treatments for metastatic breast cancer.

The trial compared people who took NERLYNX plus capecitabine with people who took lapatinib plus capecitabine. Participants were randomly selected to receive NERLYNX.

NERLYNX is taken with capecitabine (an oral chemotherapy) to help prevent the cancer from spreading any further.

SELECT IMPORTANT SAFETY INFORMATION

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

- 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.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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NERLYNX PLUS
CAPECITABINE REDUCED
THE RISK OF CANCER
PROGRESSING BY

24%

In the clinical trial, NERLYNX plus capecitabine reduced the risk of cancer progressing.^k



In the clinical trial, NERLYNX plus capecitabine also gave people a longer response to treatment compared to lapatinib plus capecitabine.^l

^kThese are relative benefits. The median progression-free survival (PFS) for NERLYNX plus capecitabine was 5.6 months vs 5.5 months in the lapatinib plus capecitabine group. In absolute numbers, using an exploratory analysis at 12 months, the PFS rate was 29% in the NERLYNX plus capecitabine group vs 15% in the lapatinib plus capecitabine group.

^lMedian duration of response of 8.5 months with NERLYNX plus capecitabine compared to 5.6 months for those taking lapatinib plus capecitabine. The 8.5 and 5.6 months durations were calculated only from the percentage of people that responded to therapy (32.8% in the NERLYNX group vs 26.7% in the lapatinib group).

SELECT IMPORTANT SAFETY INFORMATION

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

- To help prevent or reduce diarrhea (continued):
 - 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.

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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HOW TO TAKE NERLYNX

NERLYNX® (neratinib) is an oral medicine that you take once a day. You will take NERLYNX in combination with capecitabine to treat metastatic breast cancer.

For 14 days, you will take 6 NERLYNX tablets once a day plus capecitabine twice a day. After 14 days, you will stop taking capecitabine for 7 days. You will continue taking NERLYNX during this time. After 7 days, you will add capecitabine back again for 14 days. The cycle keeps repeating until the cancer progresses or side effects become too severe.

NERLYNX

Take 6 NERLYNX tablets once a day, every day.



CAPECITABINE

Take capecitabine twice a day for 14 days and then take 7 days off.



Talk to your doctor about how to take NERLYNX and capecitabine. You will also take loperamide (Imodium®), an antidiarrheal, during the first 2 months of NERLYNX treatment and then as needed. Talk to your doctor about how much and how often to take this medicine.

Your doctor may start you on the full dose of 6 tablets of NERLYNX. This dose may be reduced if you are not able to tolerate the side effects. When taking NERLYNX along with capecitabine, your doctor may reduce your dose of NERLYNX up to 2 times—down to 4 tablets and then to 3 tablets.

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MANAGING SIDE EFFECTS

“ My doctor and I figured out how to work around the side effects and not let them interfere too much with my life. ”

- patient treated with NERLYNX

Not an actual patient.

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PLANNING FOR SIDE EFFECTS

There are steps you can take to help manage the side effect of diarrhea and commit to staying on treatment. Be prepared by having a plan in place. Starting antidiarrheal medicines with the first dose of NERLYNX® (neratinib) and continuing during the initial months may help manage diarrhea.

DIET AND LIFESTYLE CHANGES CAN ALSO HELP

- Choose foods that are low in fiber and high in protein and potassium.
- Eat smaller, more frequent meals.
- Stay well hydrated by drinking 8 to 10 large glasses of clear liquid daily.
- Avoid dairy products (except for yogurt).
- Eat bananas, rice, applesauce, and toast (the BRAT diet).
- Try probiotics (found in yogurt or dietary supplements) to aid digestion.

^mThis 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.

We'll cover the cost of antidiarrheal medicines.^m

- Patients can receive up to a 3-month supply of products used for antidiarrheal treatment for free.
- Ask your healthcare team for information about a voucher for this program.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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OTHER COMMON SIDE EFFECTS

While diarrhea is the most common side effect of taking NERLYNX® (neratinib), you may experience others.

Here are some other commonly reported side effects when NERLYNX is used alone to treat early-stage breast cancer:

- 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

Here are some other commonly reported side effects when NERLYNX is used in combination with capecitabine to treat metastatic breast cancer:

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

Please see additional IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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IMPORTANT TIPS FOR TAKING NERLYNX

- Take NERLYNX® (neratinib) 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.



It's a good idea to keep a journal of your experience while taking NERLYNX so that you remember the details when you talk to your doctor.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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ONGOING **SUPPORT**

Not an actual patient.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying Patient Information.

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STAY MOTIVATED WITH THE MENTOR PROGRAM

When you start taking NERLYNX® (neratinib), the mentor program connects you with someone who currently takes or has taken NERLYNX and can share their experience with you.

Hearing from someone who has taken NERLYNX helps you:

- Learn about another person's real-life experiences with NERLYNX
- Understand why they felt NERLYNX was right for them
- Learn about the resources available as you take NERLYNX

To sign up for the **NERLYNX Mentor Program**, go to nerlynx.com/mentorship-program or call 1-855-816-5421.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

nerlynx®
(neratinib) tablets

Once you are prescribed NERLYNX® (neratinib), Puma Patient Lynx™ offers programs and services that provide ongoing education and support.



TEXT SUPPORT PROGRAM

When you sign up for the text support program, you'll 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
- Get the most out of your healthcare appointments

To sign up for free,ⁿ text LYNX to 82866.

ⁿAt no cost with an unlimited texting plan; otherwise, message and data rates may apply. Message frequency determined by user. Text HELP to 82866 for help. Text STOP to 82866 to cancel. For terms, visit carespeak.com/terms. For privacy, visit carespeak.com/privacy.



NURSE SUPPORT

Puma Patient Lynx is staffed with registered nurses who are available to answer any questions you may have about NERLYNX.

**To talk to a nurse, call 1-855-816-5421, Monday through Friday,
9 AM – 8 PM ET.**

Bilingual nurses are available.



FINANCIAL AND REIMBURSEMENT SUPPORT

Puma is committed to ensuring that financial barriers do not prevent anyone from getting NERLYNX® (neratinib). We offer:

- NERLYNX Quick Start, providing a 3-week supply of NERLYNX to eligible patients whose access to medicine is delayed
- Co-pay support for patients with commercial insurance. Eligible patients may pay as little as \$10 per prescription.^o Patients will be enrolled through their specialty pharmacy

^oLimitations 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.

- A patient assistance program that can provide free product to eligible patients
- A supportive care voucher, providing a 3-month supply of antidiarrheals free of charge. Redeem with a prescription at any retail pharmacy^p

^pThis 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.

Need financial support for taking NERLYNX? Call Puma Patient Lynx™ at 1-855-816-5421.



SPECIALTY PHARMACY SERVICES

NERLYNX is available through specialty pharmacies that help with much more than filling your prescription. They provide:

- Understanding of your insurance coverage and help if there are access issues
- On-time delivery of NERLYNX
- Nurses and pharmacists who can help with questions about NERLYNX and side effect management

For more information about delivery of NERLYNX through a specialty pharmacy, see pages 27 and 28.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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PLAN FOR SUCCESS

Before starting NERLYNX® (neratinib), it's a good idea to have a plan in place to help you start and stay on treatment. Here are some key things to have in place as you begin:



Prescription from your doctor



Plan made with healthcare team for managing side effects if they occur

(See page 19.)



Antidiarrheal medicines on hand

(Check out how to get these for free on page 19.)



Mentor call set up for information and support

(See page 23.)



Nurse Support number added to your phone

(See page 24.)

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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(neratinib) tablets

DIRECT-TO-YOUR-DOORSTEP DELIVERY

Once your doctor prescribes NERLYNX® (neratinib) and submits your prescription, you will get a phone call to start the delivery process. The number may be an 800 number or another one that is unrecognizable to you, or it may even come up as potential spam. But this call is critical to confirm your prescription before you can get the medicine. A specialty pharmacy will ship NERLYNX directly to your doorstep. **NERLYNX is not available at your local drugstore.**

Here's how it works:



1. Prescription is sent

Your doctor will submit your prescription information to either a specialty pharmacy or the Puma Patient Lynx™ support program.



In addition to NERLYNX, your doctor will also likely prescribe loperamide (Imodium®), an antidiarrheal, to help manage the side effect of diarrhea during the first 2 months.

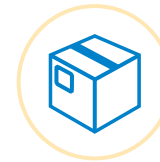


2. A phone call is made

A representative from the specialty pharmacy or a Puma Patient Lynx Oncology Nurse Advocate will process the prescription and call you to arrange for delivery.



If you haven't received this call within a few days of your doctor's appointment, reach out to your doctor's office to follow up.



3. NERLYNX is shipped

Once all the details have been confirmed, NERLYNX will be shipped directly to your home.



If your NERLYNX hasn't arrived within 5 days after your call, contact your specialty pharmacy or Puma Patient Lynx.

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

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(neratinib) tablets

APPROVED SPECIALTY PHARMACIES

Six different specialty pharmacies are available to deliver your NERLYNX® (neratinib) to you:

AcariaHealth™

T: 1-800-511-5144

acariahealth.com

Hours of operation:

M – F, 8 AM – 10 PM ET

Biologics, Inc.

T: 1-800-850-4306

biologicsinc.com

Hours of operation:

M – F, 8 AM – 8 PM ET

Optum® Specialty Pharmacy

T: 1-855-427-4682

specialty.optumrx.com

Hours of operation:

Every day, 7 AM – 10 PM CT

Accredo® Health Group, Inc.

T: 1-877-732-3431

accredo.com

Hours of operation:

M – F, 8 AM – 11 PM ET

CVS Caremark® Specialty Pharmacy

T: 1-844-239-4761

cvscaremarkspecialtyrx.com

Hours of operation:

M – F, 8:30 AM – 8:30 PM ET

Onco360®

T: 1-877-662-6633

onco360.com

Hours of operation:

M – F, 8 AM – 7 PM ET

Sat, 9 AM – 2 PM ET



Once your doctor prescribes NERLYNX, Puma Patientlynx offers programs and services that provide ongoing education and financial support. Contact a Puma Patientlynx Oncology Nurse Advocate to learn more.

T: 1-855-816-5421

nerlynx.com

Hours of operation:

M – F, 9 AM – 8 PM ET

Please see IMPORTANT SAFETY INFORMATION throughout this brochure and the accompanying [Patient Information](#).

nerlynx[®]
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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.**

Please see additional IMPORTANT SAFETY INFORMATION on next page and the accompanying [Patient Information](#).

- 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.

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IMPORTANT SAFETY INFORMATION (CONT.)

- 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
 - 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:

- 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

The most common side effects of NERLYNX in combination with capecitabine include:

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

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.

Please see accompanying
[Patient Information.](#)

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QUESTIONS ABOUT NERLYNX?



Talk to your doctor
and share this brochure
with him or her.



Visit nerlynx.com.



Call 1-855-816-5421
to talk to a team of
registered nurses.

FOLLOW OR SUBSCRIBE:



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Herceptin is a registered trademark of Genentech, Inc.

Imodium is a registered trademark of Johnson & Johnson Consumer Inc.

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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:
 - 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

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

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

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.

Manufactured for: Puma Biotechnology, Inc. 10880 Wilshire Blvd., Suite 2150 Los Angeles, CA 90024-4106

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