

TAKE A STAND.

Sherry H, treated
with NERLYNX

Against HER2+
breast cancer recurrence
and progression

Your guide to getting started with NERLYNX

What is NERLYNX tablets?

- 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.

SELECT IMPORTANT SAFETY INFORMATION

The most serious risks of NERLYNX are diarrhea and liver problems. NERLYNX can also harm your unborn baby. You should use effective birth control during treatment and for at least one month after your last dose of NERLYNX.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the [NERLYNX website](#).

You're not in this alone.

About

1 in 5

people with breast cancer have HER2+ breast cancer

HER2+: human epidermal growth factor receptor 2–positive

A HER2 gene mutation can cause cells to make too much of the HER2 protein. This means cells behave more aggressively and grow faster than normal. **You can be diagnosed with early-stage or metastatic HER2+ breast cancer:**

Early-Stage

Early-stage HER2+ breast cancer is cancer that **has not spread beyond the breast and the nearby lymph nodes.**

Metastatic

Metastatic HER2+ breast cancer, also called stage IV breast cancer, is cancer that **has spread beyond the breast and nearby lymph nodes** to other parts of the body.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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How to use this brochure

Whether you're thinking about starting or have been prescribed NERLYNX, you're taking an active role in protecting against HER2+ breast cancer recurrence or progression.

Use the table of contents below to find the information most relevant to where you are in your treatment. While the information you'll find can help you better understand NERLYNX and what to expect with treatment, it should not be used in place of your doctor's advice. Be sure to work closely with your care team so you can be confident in your treatment decisions.

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Turn to [page 19](#) for questions to help you start a conversation about NERLYNX with your doctor

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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What is NERLYNX® (neratinib)?

NERLYNX is a once daily treatment taken by mouth. It is approved to treat both early-stage and metastatic HER2+ breast cancer.

When could your doctor prescribe NERLYNX?

Early-Stage (stages I-III)

NERLYNX for **early-stage HER2+ breast cancer** may help reduce the risk of **recurrence** after adjuvant trastuzumab-based therapy (another HER2-targeted treatment).

Metastatic (stage IV)

NERLYNX for **advanced or metastatic HER2+ breast cancer** is taken in combination with a medication called capecitabine after at least 2 other anti-HER2 therapies. NERLYNX may help **protect against progression**.



Neoadjuvant therapy: Treatment before surgery may help shrink tumors and decrease the chance of cancer cells spreading. How your tumor responds to neoadjuvant treatment may help determine which therapies will work best after surgery.

Surgery and/or radiation: You may require surgery to remove the tumor from the breast, with or without a biopsy to test underarm lymph nodes. Before or after surgery, your care team may also recommend that you undergo radiation, using high-energy x-rays to destroy cancer cells.

Adjuvant therapy: Treatment after surgery or radiation is also intended to destroy cancer cells. Residual cancer, hormone receptor status, age, and other factors will determine what treatment your care team recommends for adjuvant therapy. If you have hormone receptor–positive (HR+) breast cancer, it may be recommended that you continue endocrine therapy for multiple years.

Extended adjuvant therapy: Extended adjuvant treatment with a HER2-targeted therapy is used to further reduce the chance of your breast cancer returning.

Remission: If your cancer is in remission, it means that it is undetectable and that symptoms have subsided.

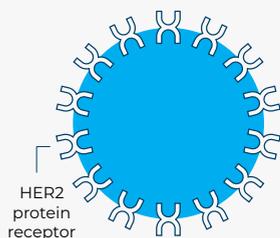
Recurrence: Recurrence is when cancer returns after a period of improvement.

Anti-HER2 therapies: Treatments that target and block HER2 protein activity. Blocking HER2 activity helps slow or stop the growth of additional HER2+ cancer cells. NERLYNX is an example of an anti-HER2 therapy.

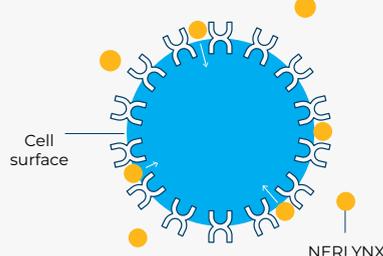
Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

How does NERLYNX work?

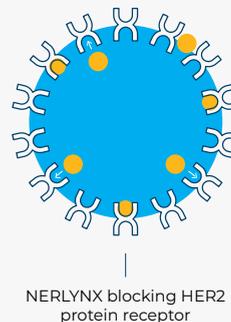
NERLYNX is a targeted therapy that works inside your cells and helps stop HER2 protein signals.



A HER2+ cancer cell has more HER2 protein receptors than usual.



NERLYNX is a small molecule, so it goes through the cell surface to work from the inside.



Once inside the cell, NERLYNX blocks HER2 receptors to help prevent cells from growing and dividing.

SELECT IMPORTANT SAFETY INFORMATION

Diarrhea is a common side effect of NERLYNX, but it can also be severe. Diarrhea may lead to loss of too much body salts and fluid, which can cause dehydration. Call your healthcare provider right away if you have severe diarrhea or if you have diarrhea along with weakness, dizziness, or fever. You may be prescribed antidiarrheals as needed. Always take antidiarrheals exactly as your healthcare provider tells you.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.



Scan or click QR code to see NERLYNX in action

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What is my risk of recurrence?

HER2+ breast cancer is different from other breast cancers. It grows quicker, tends to be more aggressive, and is more likely to come back or spread, even after adjuvant treatment. If your cancer comes back after a period of remission, this is called **recurrence**.

One analysis found that about

25%

of early-stage HER2+ breast cancer
patients experienced recurrence within 10 years

What can I do to reduce my risk of recurrence?

With breast cancer, there is always some level of risk that the cancer will return. Regardless of when you were diagnosed, it's important to know what's ahead so you and your care team can make a plan.

Taking NERLYNX for just 1 year after adjuvant trastuzumab-based treatment may help reduce your risk of recurrence

SELECT IMPORTANT SAFETY INFORMATION

The most serious risks of NERLYNX are diarrhea and liver problems. NERLYNX can also harm your unborn baby. You should use effective birth control during treatment and for at least one month after your last dose of NERLYNX.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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How was NERLYNX studied in early-stage HER2+ breast cancer?

NERLYNX was studied in a phase 3 clinical trial called ExteNET. The safety and effectiveness of NERLYNX were evaluated over 2 years in women with early-stage HER2+ breast cancer.

Who was in the study?

- The study included 2,840 women with either hormone receptor–positive (HR+) or hormone receptor–negative (HR–) early-stage HER2+ breast cancer
- All women had previously completed trastuzumab-based treatment

What were the treatment groups in this study?

- Those in the study were randomly assigned to a treatment group: 1,420 received NERLYNX and 1,420 received placebo (an inactive substance that looked the same as and was given the same way as NERLYNX). The effects of NERLYNX were compared to the effects of the placebo

Please see [Important Safety Information on pages 24-25](#) and [Patient Information on the NERLYNX website](#).



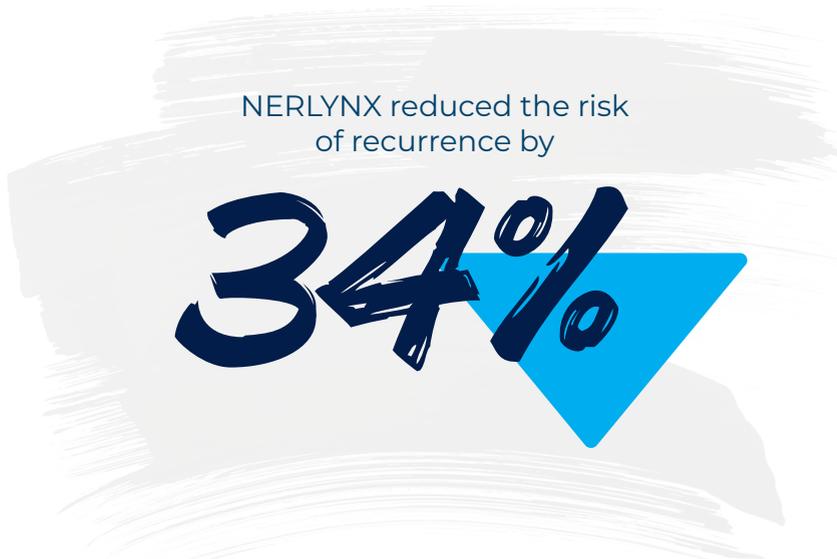
“This is a fighting chance to help reduce my risk... So I took it.”

— Sherry H, treated with NERLYNX

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How effective was NERLYNX in women with early-stage HER2+ breast cancer?

Effectiveness was primarily measured by comparing recurrence between treatment groups after 2 years. NERLYNX is prescribed to be taken continuously for 1 year (unless your breast cancer returns).



In absolute numbers, 94.2% of the 1,420 women who took NERLYNX in the study did not have cancer return after 2 years, compared to 91.9% of the 1,420 women who took placebo.

Individual results may vary.

SELECT IMPORTANT SAFETY INFORMATION

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.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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***Talk to your doctor
to help you understand
what these numbers
may mean for you and your
treatment with NERLYNX***



Erin B, treated
with NERLYNX

Sherry H, treated
with NERLYNX

Please see [Important Safety Information](#) on pages 24-25
and [Patient Information](#) on the NERLYNX website.

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Are there additional data on NERLYNX in women with early-stage HER2+ breast cancer that is HR+?

After the main portion of the trial, 75% of the women (2,117 out of 2,840) agreed to continue being evaluated. At 5 years from the start of the original trial, a special analysis looked at 1,334 of the women with HR+ breast cancer. Of these women, 670 started NERLYNX and 664 started placebo within 1 year of treatment with trastuzumab. Most of these women received endocrine therapy while on NERLYNX.

A reduction in the risk of recurrence was observed. Of these women, the 5-year analysis found that those who completed NERLYNX as prescribed had an even lower risk of recurrence.*

42%

reduction in the risk of recurrence

90.8% of the 670 women in the NERLYNX group did not have their cancer return after 5 years, compared to 85.7% of the 664 women who took placebo.

Individual results may vary.

* Completion of treatment was defined as 11 months or more of treatment or NERLYNX treatment that ended after less than 11 months due to disease recurrence. The primary measure of effectiveness in the NERLYNX clinical trial was reduction in risk of recurrence in early-stage HER2+ breast cancer over 2 years. Please see page 8 for more information.

SELECT IMPORTANT SAFETY INFORMATION

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.

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Is there more from the 5-year special analysis that I should know about?

This 5-year analysis also observed a **59% reduction in the risk of central nervous system (CNS) metastases** among women with early-stage HER2+ HR+ breast cancer who started NERLYNX within 1 year of treatment with trastuzumab. This suggests that in the clinical trial, these women were less likely to experience a recurrence in the brain or spinal cord, or die from any cause.

In absolute numbers, 98.4% of the 670 women who took NERLYNX did not experience a CNS recurrence, or death from any cause, compared to 95.7% of the 664 women who took placebo.

Individual results may vary.

**When you're reducing your risk of recurrence,
every day of treatment counts**

SELECT IMPORTANT SAFETY INFORMATION

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.

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What side effects could I experience while taking NERLYNX?

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

- Diarrhea
- Vomiting
- Nail problems including color change
- Nausea
- Rash
- Dry skin
- Stomach-area (abdomen) pain
- Dry or inflamed mouth, or mouth sores
- Swelling of your stomach-area
- Tiredness
- Decreased appetite
- Nosebleed
- Muscle spasms
- Weight loss
- Upset stomach
- Urinary tract infection



Women in the NERLYNX clinical trial were not required to take antidiarrheal medicine. Be sure to talk to your care team about any side effects you have. They may be able to help you find ways to manage them. Your healthcare team may change your dose of NERLYNX, temporarily stop, or permanently stop treatment with NERLYNX if you have certain side effects.

Please see [Important Safety Information on pages 24-25](#) and [Patient Information on the NERLYNX website](#).

Find tips for managing side effects on [page 18](#)

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How do I take NERLYNX?

NERLYNX is a once daily medicine that you take by mouth. Talk to your doctor about the correct dosage for you, which will determine how many tablets you take each day. **NERLYNX is taken:**



Your doctor may also decide to use dose escalation to help manage side effects. Dose escalation is when you gradually increase your dose of NERLYNX over time. **Here's an example of what dose escalation with NERLYNX may look like:**



A full dose of NERLYNX is 6 tablets (240 mg) once daily

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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Is NERLYNX right for me?

If you've already been treated with 2 or more HER2-directed therapies for metastatic breast cancer (like trastuzumab, ado-trastuzumab emtansine [T-DM1], and/or pertuzumab), NERLYNX + capecitabine may be right for you.

How was NERLYNX studied in metastatic breast cancer?

NERLYNX was studied in NALA, a phase 3 clinical trial that measured the effectiveness and safety of NERLYNX in combination with capecitabine (a chemotherapy treatment taken by mouth) compared to lapatinib (another HER2-directed treatment) + capecitabine.

Who was in the study?

- 621 people with metastatic HER2+ breast cancer were enrolled
- All participants had previously been treated with **at least 2** other HER2-directed therapies

What were the treatment groups in this study?

- Those in the study were randomly assigned to a treatment group: 307 received NERLYNX + capecitabine, and 314 received lapatinib + capecitabine
- People in the NERLYNX + capecitabine group received loperamide (an antidiarrheal) for the first 3 weeks of treatment

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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*“Things have changed
and there are more targeted
therapy options available.”*

—Erin B, treated with NERLYNX

How effective was NERLYNX + capecitabine in people with metastatic HER2+ breast cancer?

One of the primary ways that effectiveness was measured was by comparing progression between treatment groups.

NERLYNX + capecitabine reduced
the risk of progression by

24%

**in those with metastatic
HER2+ breast cancer**

These are relative benefits. In absolute numbers, 29% of the 307 people in the NERLYNX + capecitabine group did not see their cancer progress over 1 year compared to 15% of the 314 people in the lapatinib + capecitabine group.

Individual results may vary.

SELECT IMPORTANT SAFETY INFORMATION

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.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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What side effects could I experience while taking NERLYNX + capecitabine?

Diarrhea is the most common side effect of taking NERLYNX, and can be severe. Diarrhea may lead to loss of too much body salts and fluid, which can cause dehydration.

Talk to your doctor about how to best manage NERLYNX side effects, and call them right away if you have severe diarrhea or experience diarrhea along with weakness, dizziness, or fever.

Here are some other commonly reported side effects when NERLYNX is used in combination with capecitabine to treat metastatic HER2+ 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



These are not all of the possible side effects of NERLYNX. Tell your healthcare provider if you have any side effects that bother you or that does not go away. **You may report side effects to Puma Biotechnology, Inc., at 1-844-NERLYNX (1-844-637-5969) or FDA at 1-800-FDA-1088.**

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

Find tips for managing side effects on [page 18](#)

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I have metastatic breast cancer. How do I take NERLYNX?

NERLYNX is an oral medicine that you take once a day. Talk to your doctor about the correct dosage for you. It's important to remember that if you're taking NERLYNX for your metastatic breast cancer, you must take it in combination with capecitabine.

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6 NERLYNX tablets, once a day, every day.



CAPECITABINE

Capecitabine is taken twice a day for 14 days, and then 7 days off. Talk to your doctor to make sure you understand how to take this medication.

Your doctor may start you on a lower dose of NERLYNX and then gradually increase to your full dosage. This is called **dose escalation**.

Here's an example of what dose escalation with NERLYNX may look like:



Week 1

3 tablets (120 mg)
Once daily



Week 2

4 tablets (160 mg)
Once daily



Week 3+

6 tablets (240 mg)
Once daily

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

What can I do to manage the most common side effect?

We know that side effects can be a challenge with any treatment, but there are things you can do to help. **Here are some tips to keep in mind that may help manage diarrhea:**



Try foods that are **low in fiber** and **high in potassium**



Avoid dairy products (except for yogurt)



Eat smaller, more frequent meals throughout the day



Try the BRAT diet: bananas, rice, applesauce, and toast



Stay well hydrated. Drink up to 8 to 12 glasses of clear liquid every day



Try probiotics, such as those in yogurt or dietary supplements, to help digestion

* At no cost with an unlimited texting plan; otherwise, message and data rates may apply. Message frequency determined by user. Text "HELP" to 82866 for assistance. Text "STOP" to 82866 to cancel. For terms and privacy: pumabiotechnology.com/ppj_terms.html.

† This is an informational service. Call center nurses do not offer medical advice.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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What resources are there to help support me and my loved ones?



Text Message Program

This FREE* text-message-based program is available to provide additional information, nutrition tips, and motivation to help you throughout your treatment with NERLYNX.

Text “LYNX” to 82866 to sign up.



Nurse Call Center†

If you have questions about NERLYNX, we have a team of registered nurses available to speak with you. Our call center is open Monday through Friday, 9 AM to 8 PM ET, for your convenience.

Call 1-855-816-5421 (when prompted, press 2) to speak with a nurse today.

QUESTIONS TO ASK YOUR DOCTOR

Help guide the conversation about NERLYNX. Visit [NERLYNX.com](https://www.nerlynx.com) to download the [Doctor Discussion Guide](#).

1

How is NERLYNX different from previous treatments I've tried?

3

What would be my treatment goal with NERLYNX?

2

How do I decide if additional treatment with NERLYNX is right for me?

4

When do you recommend that I start taking NERLYNX and how long will I be taking it?

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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WE STAND TOGETHER.

If you are considering or already being treated with NERLYNX, our mentor program connects you with someone who currently takes or has taken NERLYNX.*

Let a mentor's story help you gain confidence in your stand against HER2+ breast cancer. While every experience with NERLYNX is unique, and your doctor should always be your primary source of information for treatment decisions, hearing from someone who has taken NERLYNX helps you:

- Understand why they felt NERLYNX was the right step for them
- Gain confidence to take this next step toward reducing recurrence or progression
- Learn about the resources available as you take NERLYNX

English-speaking and bilingual mentors are ready to connect with you.

*The mentor program is here for you with support and resources. Your healthcare team should always be your primary source of information for treatment decisions. Puma mentors are compensated for their time.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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To talk to a mentor,
call 1-855-816-5421

Scan or click QR code to sign up for the mentor program

**Valerie M, treated
with NERLYNX**



**Irmalay S, treated
with NERLYNX**



**Sherry H, treated
with NERLYNX**



**Erin B, treated
with NERLYNX**



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ABOUT
NERLYNX

EARLY-STAGE
BREAST CANCER

METASTATIC
BREAST CANCER

NERLYNX
SUPPORT

IMPORTANT SAFETY
INFORMATION

What financial assistance could be available to me?



Patient Assistance Program

NERLYNX is provided free to those who are uninsured and meet certain financial qualifications. Information on nonprofit foundations and other potential resources for those who need financial support can be provided. For information or assistance with pharmacy insurance benefits, call 1-855-816-5421.



NERLYNX Quick Start

This program provides a 3-week supply of NERLYNX to those eligible whose access to medicine is delayed.



Co-pay Support

Those who are commercially insured, eligible, and treated with NERLYNX may be enrolled through their specialty pharmacy or clinic to pay as little as \$10 per prescription.*

* Patient must have commercial insurance. Offer is not valid under Medicare, Medicaid, or any other federal or state program.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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How do I get NERLYNX?

You can fill your NERLYNX prescription through a specialty pharmacy or select designated pharmacies. If you select a specialty pharmacy, once your doctor submits your prescription, you will receive a phone call to start the delivery process. You may not recognize the phone number, but it's important to answer the call to confirm your prescription and shipment information with the specialty pharmacy.

In addition to your prescription, specialty pharmacies can provide:



Understanding of your insurance coverage and help with access and financial issues



Timely delivery of NERLYNX



Nurses and pharmacists who can help with questions about NERLYNX and side effect management



A voucher from Puma, the company that makes NERLYNX, for a 3-month supply of certain antidiarrheal medicines when prescribed by your doctor*

* Limitations apply. Puma Biotechnology reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, call Puma Patient Lynx™ at 1-855-816-5421.

Please see [Important Safety Information](#) on pages 24-25 and [Patient Information](#) on the NERLYNX website.

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IMPORTANT SAFETY INFORMATION

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

NERLYNX may cause serious side effects, including:

- **Diarrhea.** Diarrhea is a common side effect of NERLYNX, but it can also be severe. Diarrhea may lead to loss of too much body salts and fluid, which can cause dehydration. Your healthcare provider will prescribe NERLYNX in one of two ways to help manage diarrhea:

Full dose of NERLYNX:

- Your healthcare provider will prescribe the antidiarrheal medicine loperamide for you during your first 2 months (56 days) of treatment with NERLYNX and then as needed. Your healthcare provider will tell you exactly how much and how often to take this medicine.
- If you are prescribed the full dose of NERLYNX from the start of your treatment, be sure that your healthcare provider also prescribes antidiarrheals with NERLYNX. You should start taking loperamide with your first dose of NERLYNX.
- After 2 months (56 days) of treatment with NERLYNX, follow your healthcare provider's instructions about taking loperamide as needed to control diarrhea.

A lower starting dose of NERLYNX:

- Your healthcare provider will start you on a lower dose of NERLYNX for the first 2 weeks of treatment and then increase you to a full dose NERLYNX regimen. Tell your healthcare provider right away if you develop diarrhea; you may be prescribed loperamide as needed.

To help prevent or reduce diarrhea during treatment with NERLYNX:

- Your healthcare provider may also need to give you additional antidiarrheals, fluids, and electrolytes to manage diarrhea when you start treatment with NERLYNX. Follow your healthcare provider's instructions on how to take antidiarrheal medicines.

- Always take antidiarrheals exactly as your healthcare provider tells you.
- While taking antidiarrheals, 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 if you have severe diarrhea or if you have diarrhea along with weakness, dizziness, or fever.**

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.

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.

Important Safety Information is continued on the following page.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

- 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 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
 - 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
- 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:

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

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

Tell your healthcare provider 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 [Patient Information on the NERLYNX website](#).

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Please see [Important Safety Information](#) on pages 24-25
and [Patient Information](#) on the NERLYNX website.



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