Questions to Ask Your Doctor About HER2+ Breast Cancer

No matter where you are in your treatment-planning process, it is important to partner with your doctor. You should work with your doctor to ensure that you are taking all appropriate steps to reduce your risk of recurrence. To help with these discussions, you should prepare a list of the right questions.

What is NERLYNX® (neratinib) 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.

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

  1. **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. 

Note: This additional treatment is sometimes referred to as extended adjuvant treatment.

But because there is a specific protein expressed in HER2+ breast cancer, there are medications, like NERLYNX, that specifically target the HER2 protein, which may make a difference.

SELECT IMPORTANT SAFETY INFORMATION

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

You may not have heard about NERLYNX, a treatment for HER2+ breast cancer, but it’s important to talk to your doctor to see if it might be right for you. NERLYNX is the only FDA-approved therapy proven to help reduce the risk of recurrence in the extended adjuvant setting for adult HER2+ breast cancer patients.

Asking your doctor about NERLYNX and recurrence risk keeps you knowledgeable about possible treatment goals and helps you think about what’s ahead. For more information on NERLYNX, download our brochure here.

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  - **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.

- 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
  - 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 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 accompanying Patient Information.