

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 fluids, and get dehydrated. Your healthcare provider should prescribe the medicine loperamide for you during your first 2 months (56 days) of NERLYNX and then as needed. To help prevent or reduce diarrhea:
 - Tell your healthcare provider if you have more than 2 bowel movements in 1 day, or you have diarrhea that does not go away.
 - **Call your healthcare provider right away, as instructed, if you have severe diarrhea or if you have diarrhea along with weakness, dizziness, or fever.**

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

See “What are the possible side effects of NERLYNX?” for more information about side effects.

What is NERLYNX?

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

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

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

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

- have liver problems. You may need a lower dose of NERLYNX.
- are pregnant or plan to become pregnant. NERLYNX can harm your unborn baby. If you are a female who can become pregnant:
 - Your healthcare provider should do a pregnancy test before you start taking NERLYNX.
 - You should use effective birth control (contraception) during treatment and for at least 1 month after your last dose of NERLYNX.
 - Talk with your healthcare provider about forms of birth control that you can use during this time.
 - Tell your healthcare provider right away if you become pregnant during treatment with NERLYNX
 - Males with female partners who can become pregnant should use effective birth control during treatment and for 3 months after 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, and H-2 receptor antagonists. 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

Common side effects of NERLYNX include:

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| • diarrhea | • decreased appetite |
| • nausea | • muscle spasms |
| • stomach-area (abdomen) pain | • upset stomach |
| • tiredness | • nail problems including color change |
| • vomiting | • dry skin |
| • rash | • swelling of your stomach-area |

- dry or inflamed mouth, or mouth sores
- weight loss
- urinary tract infection

These are not all the possible side effects of NERLYNX.

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