

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. 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.

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.
- 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 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.

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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For more information, go to www.NERLYNX.com or call 1-844-637-5969.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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