Neratinib (Nerlynx®)

**Pronounced:** ner-a-ti-nib

**Classification:** Kinase inhibitor

**About Neratinib (Nerlynx®)**

Neratinib works by targeting and blocking EGFR and HER kinase. In some cancers, these receptors are overactive, causing cells to grow and divide too fast. By blocking these particular enzymes from working, this medication can slow the growth of cancer cells. Your oncology team will test your tumor for the over activity of these kinases, which must be present in order to receive the medication.

**How to Take Neratinib**

This medication comes in tablet form to be taken by mouth, once a day with food, at about the same time each day. You will need to take multiple tablets to make up the dose. Tablets should be swallowed whole; do not chew, crush, or break them. If you miss a dose, skip that dose and take the next dose at your regularly scheduled time. Do not take 2 doses at the same time to make up for a missed dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. Foods to avoid include: grapefruit, grapefruit juice and Seville oranges. Medications that can interfere with this medication include: clarithromycin, ritonavir, diltiazem, elvitegravir, itraconazole, ketoconazole, posaconazole, voriconazole, aprepitant, ciprofloxacin, clotrimazole, dronedarone, erythromycin, fluconazole, fluvoxamine, verapamil, carbamazepine, phenytoin, rifampin, St. John’s wort, etravirine, modafinil, digoxin, dabigatran, and fexofenadine, among others. Be sure to tell your healthcare provider about all medications and supplements you take.

You should not take neratinib at the same time as "heartburn" medications, as these may affect how your cancer medication is absorbed. These include proton pump inhibitors such as Prilosec (omeprazole), Nexium (esomeprazole), Protonix (pantoprazole) and H2 blockers, such as Pepcid (famotidine). Antacids, such as Tums (calcium-carbonate) and Rolaid (Calcium Carbonate and Magnesium Hydroxide) can be taken if spaced out from the neratinib dose by at least 3 hours (before or after). If needed, please ask your care team the best “heartburn” medication to use and when to take it.

**Storage and Handling**

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

**Where do I get this medication?**
Neratinib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

**Insurance Information**

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

**Possible Side Effects of Neratinib**

There are a number of things you can do to manage the side effects of neratinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Diarrhea**

This medication can cause diarrhea that can be severe and lead to serious dehydration and death. Your oncology team will provide instructions for taking the anti-diarrheal medication loperamide. Notify your oncology team if you develop diarrhea or if you have more than 2 bowel movements in a day.

Your oncology care team can recommend additional medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole-grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Abdominal Pain**

Your healthcare provider can recommend medications and other strategies to help relieve pain.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Skin and Nail Changes**

Neratinib has some less common, but unique nail and skin side effects that you should be aware of and notify your care team if you develop. Patients may develop a rash. While this rash may look like acne, it is not, and should not be treated with acne medications. The rash may appear red, swollen, crusty, dry and feel sore. You may also develop very dry skin, which may crack, be itchy or become flaky or scaly. The rash typically starts in the first week of treatment, but can occur at any time during treatment. Tips for managing your skin include:

- Use a thick, alcohol-free emollient lotion or cream on your skin at least twice a day, including right after bathing.
- Avoid sun exposure, as it can worsen the rash or cause a severe burn. Use a sunscreen with an SPF of 30 or higher and wear a hat and sunglasses to protect your head and face from the sun.
• Bathe/shower in cool or lukewarm (not hot) water and pat your skin dry.
• Use soaps, lotions and laundry detergents without alcohol, perfumes or dyes.
• Wear gloves to wash dishes or do housework or gardening.
• Drink plenty of water and try not to scratch or rub your skin.
• Notify your healthcare team if you develop a rash, as they can provide suggestions to manage the rash and/or prescribe a topical medication to apply to the rash or an oral medication.
• If you develop peeling or blistering of the skin, notify your healthcare team right away.

While receiving neratinib, you may develop an inflammation of the skin around the nail bed/cuticle areas of toes or fingers, which is called paronychia. It can appear red, swollen or pus filled. Nails may develop “ridges” in them or fall off. You may also develop cuts or cracks that look like small paper cuts in the skin on your toes, fingers or knuckles. These side effects may appear several months after starting treatment, but can last for many months after treatment stops.

• Follow the same recommendations for your skin (above).
• Don’t bite your nails or cuticles or cut the cuticles.
• Keep your fingernails and toenails clean and dry.
• You may use nail polish, but do not wear fake nails.
• Notify your doctor or nurse if any nails fall off or you develop any of these side effects or other skin abnormalities

**Mouth Ulcers (Sores)**

Certain cancer treatments can cause sores or soreness in your mouth and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing regular mouth care can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

• Brush with a soft-bristle toothbrush or cotton swab twice a day.
• Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is recommended 4 times daily.
• If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
• Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

**Muscle Spasms**

Your healthcare provider can recommend medications and other strategies to help relieve pain.

**Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team will monitor for using blood tests called liver function tests. You will have these blood tests monthly for the first 3 months, then every 3 months while on this medication. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 1 month after the last dose for females and 3 months after the last dose for males. Contraception should be used even if your menstrual cycle stops or you believe you are not producing sperm. You should not breastfeed while receiving this medication, or for 1 month after your last dose.