

Package leaflet: Information for the patient

Nerlynx 40 mg film-coated tablets neratinib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of Section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Nerlynx is and what it is used for
2. What you need to know before you take Nerlynx
3. How to take Nerlynx
4. Possible side effects
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1. What Nerlynx is and what it is used for

What Nerlynx is

Nerlynx contains the active substance ‘neratinib’. It belongs to a group of medicines called ‘tyrosine kinase inhibitors’ used to block cancer cells and treat breast cancer.

What Nerlynx is used for

Nerlynx is used for patients who have early stage breast cancer which:

- is hormone receptor positive (HR-positive) and human epidermal growth factor receptor 2-positive (HER2-positive), and
- has previously been treated with another medicine called ‘trastuzumab’.

The ‘HER2 receptor’ is a protein found on the surface of cells in the body. It helps control how a healthy breast cell grows. In HER2-positive breast cancer, the cancer cells have a large amount of HER2 receptors on their surface. This results in the cancer cells dividing and growing faster. ‘Hormone receptors’ are also proteins expressed inside the cells of some specific tissues. Estrogens and progesterone bind to these proteins and regulate cell activity. In HR-positive breast cancer, tumor cell division and growth can be enhanced by estrogens and/or progesterone.

Before Nerlynx is used, your cancer must have been tested to show it is HR-positive and HER2-positive. You must also have previously been treated with trastuzumab.

How Nerlynx works

Nerlynx works by blocking the HER2 receptors on the cancer cells. This helps to stop the cells from dividing and growing.

2. What you need to know before you take Nerlynx

Do not take Nerlynx

- if you are allergic to neratinib or any of the other ingredients of this medicine (listed in Section 6),
- if you have a severe liver problem,
- if you are taking rifampicin (a medicine for tuberculosis (TB)),
- if you are taking carbamazepine or phenytoin (medicines for seizures),
- if you are taking St. John's wort (herbal product for depression).

Warnings and precautions

Talk to your doctor or pharmacist before taking Nerlynx.

You need to take an anti-diarrhoea medicine when you start Nerlynx

Nerlynx can cause diarrhoea early during treatment. You should take an anti-diarrhoea medicine so that your diarrhoea does not become severe, and to prevent you from getting dehydrated during treatment with Nerlynx.

Tests and checks for liver problems

Nerlynx can cause changes in liver function – these are shown in blood tests. Your doctor will do blood tests before and during your treatment with Nerlynx. Your doctor will stop your treatment with Nerlynx if your liver tests show severe problems.

Children and adolescents

Do not use in children under 18 years of age. The safety of Nerlynx and how effective it is has not been studied in this age group.

Other medicines and Nerlynx

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Nerlynx can affect the way some other medicines work. Also some other medicines can affect the way Nerlynx works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin - a medicine for tuberculosis
- carbamazepine, phenobarbital, or phenytoin - medicines for seizures
- St John's wort - an herbal product for depression
- ketoconazole, voriconazole, itraconazole or fluconazole - medicines for fungal infections
- erythromycin or clarithromycin - medicines for bacterial infections
- protease inhibitors - antiviral medicines
- nefazodone – a medicine to treat depression
- diltiazem or verapamil - medicines for high blood pressure and chest pain
- dabigatran or digoxin - a medicine for heart problems
- rosuvastatin – a medicine to treat high cholesterolemia
- irinotecan – a medicine used in colorectal cancers
- sulfasalazine – an anti-inflammatory intestinal medicine
- medicines for stomach problems such as:
 - lansoprazole, omeprazole or similar medicines called 'proton pump inhibitors' or PPIs are not recommended.
 - ranitidine, cimetidine or similar medicines called "H₂ receptor antagonists". Neratinib should be taken 10 hours after the H₂-receptor antagonist dosing and at least 2 hours before the next dose of the H₂-receptor antagonist
 - antacid medicines - the dose of these medicines and Nerlynx should be separated by at least 3 hours.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Nerlynx.

Nerlynx with food and drink

Do not take grapefruit or pomegranate while you are taking Nerlynx – this includes eating them, drinking the juice or taking a supplement that might contain them. This is because these fruits may interact with Nerlynx and affect how the medicine works.

Pregnancy

If you are pregnant, the doctor will assess the potential benefit to you and risk to the foetus before giving this medicine to you. If you become pregnant while taking this medicine, the doctor will assess the potential benefit to you and the risk to the foetus, of continuing this medicine.

Contraception

Women who can become pregnant must use an effective method of contraception, including a barrier method:

- while taking Nerlynx and
- for one month after treatment has finished.

Men must use an effective barrier method of contraception such as a condom:

- while taking Nerlynx and
- for three months after treatment has finished.

Breast-feeding

Talk to your doctor before taking Nerlynx if you are breast-feeding or plan to breast-feed because small amounts of this medicine may pass into your breast milk. Your doctor will discuss with you the benefits and risks of taking Nerlynx during this time.

Driving and using machines

Nerlynx has minor or moderate influence on the ability to drive and use machines. The side effects of Nerlynx (for example, dehydration and dizziness resulting from diarrhoea, fatigue, and fainting) may affect how tasks that require judgment, motor or cognitive skills are carried out.

3. How to take Nerlynx

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much Nerlynx to take

The recommended dose of Nerlynx is 6 tablets once a day (a total of 240 mg).

- Take the tablets with food. Do not crush or dissolve. Do not swallow the desiccant.
- Take all the tablets with water, at about the same time each day, preferably in the morning.

The course of treatment is one year.

You need to take an anti-diarrhoea medicine when you start Nerlynx

Nerlynx can cause diarrhoea early during treatment unless anti-diarrhoea medicine is taken to prevent or reduce diarrhoea. Diarrhoea usually happens early in treatment with Nerlynx and may be severe, causing you to get dehydrated.

- Start taking anti-diarrhoea medicine with the first dose of Nerlynx.
- Your doctor will tell you how to take the anti-diarrhoea medicine.
- Keep taking anti-diarrhoea medicine during the first one to two months of Nerlynx treatment. Your doctor will tell you if you need to keep taking anti-diarrhoea medicine after the first two months to control your diarrhoea.
- Your doctor will also tell you if you need to change the dose of Nerlynx because of diarrhoea.

If you take more Nerlynx than you should, contact a doctor or a hospital straight away. Take the medicine pack with you.

Some side effects associated with taking more Nerlynx than you should are: diarrhoea, nausea, vomiting and dehydration.

If you forget to take Nerlynx

- If you forget a dose, wait until the next day before you take the next dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Nerlynx

- Do not stop taking Nerlynx without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Diarrhoea

Nerlynx can cause diarrhoea early during treatment unless anti-diarrhoeal medicines are taken to prevent or reduce diarrhoea. The diarrhoea may be severe, and you may get dehydrated. See Section 3 for more information about the anti-diarrhoea medicine you need to take at the same time as Nerlynx.

Talk to your doctor if:

- you are having diarrhoea that does not go away - they can advise how to control your diarrhoea.
- you feel dizzy or weak from diarrhoea - alternatively go to the hospital immediately.

Liver problems

Nerlynx can cause changes in liver function - these are shown in blood tests. You may or may not have signs or symptoms of liver problems (e.g., yellow skin and/or eyes, dark urine, or light-colour stools). Your doctor will do blood tests before and during your treatment with Nerlynx. Your doctor will stop your treatment with Nerlynx if your liver tests show severe problems.

Other side effects

Tell your doctor or pharmacist if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people

- diarrhoea
- stomach pain, feeling or being sick, low appetite
- dry or inflamed mouth, including blisters or mouth ulcers
- rash
- muscle spasms or cramps
- feeling very tired

Common: may affect up to 1 in 10 people

- burning sensation during urination and frequent, and urgent need to urinate, (may be symptoms of urinary tract infection)
- dehydration
- fainting
- nosebleed
- mild stomach upset
- dry mouth
- changes in liver blood test results
- nail problems including nail splitting or colour change
- dry skin including cracked skin
- changes in kidney function test
- weight loss

Uncommon: may affect up to 1 in 100 people

- kidney failure
- changes in liver blood test results (i.e., blood bilirubin increased)

Tell your doctor or pharmacist if you notice any of the side effects above.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nerlynx

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

Keep the bottle tightly closed in order to protect from moisture.

This medicinal product does not require any special temperature storage conditions.

Do not use Nerlynx if you notice any signs of damage to the packaging or if there are any signs of tampering (e.g., inner seal is broken).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nerlynx contains

- The active substance is neratinib. Each film-coated tablet contains neratinib maleate, equivalent to 40 mg neratinib.
- The other ingredients are:
 - Tablet core: mannitol (E421), microcrystalline cellulose, crospovidone, povidone, colloidal anhydrous silica, magnesium stearate
 - Tablet coating: polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide red (E172)

What Nerlynx looks like and contents of the pack

The film-coated tablets are red oval shaped and debossed with 'W104' on one side and plain on the other side.

Nerlynx film-coated tablets are packaged in a white, high-density polyethylene (HDPE) round bottle with child-resistant, polypropylene closure, and foil induction inner seal for a tamper-evident seal. Each bottle contains 180 film-coated tablets.

An HDPE desiccant canister with 1 g silica gel is enclosed with the tablets in each bottle. Do not swallow the desiccant.

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