

NERLYNX[®] FILM-COATED TABLETS

Neratinib (40mg)

What Is In This Leaflet

1. What Nerlynx is used for
2. How Nerlynx works
3. Before you use Nerlynx
4. How to use Nerlynx
5. While you are using it
6. Side effects
7. Storage and Disposal of Nerlynx
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

This leaflet answers some common questions about Nerlynx Tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Nerlynx against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

1. What Nerlynx Is Used For

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

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

- is 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.

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

2. How Nerlynx works

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is only available with a prescription from a doctor experienced with chemotherapy treatment.

3. Before you use Nerlynx

When you must not use it

You should not take this medicine if you have an allergy to:

- neratinib
- any of the other ingredients of this medicine, listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You should not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

1) Are pregnant or plan to become pregnant

Nerlynx is not recommended for use during pregnancy. There is no information about the safety of this medicine in pregnant women.

However if there is a need to take this medicine when you are pregnant, your doctor will discuss the risks and benefits to you and the unborn baby.

If you become pregnant while taking this medicine, the doctor will assess the potential benefit to you and the risk to the unborn baby, of continuing this medicine.

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.

2) Are breast-feeding or plan to breastfeed

It is not known whether Nerlynx passes into breast milk. Do not breastfeed during treatment and for at least 1 month after your last dose of NERLYNX.

Talk to your doctor before taking this medicine 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.

3) Have any gastrointestinal problems

Nerlynx can cause diarrhoea when you first start taking it. You should take an anti-diarrhoea medicine called loperamide so that your diarrhoea does not become severe, and to prevent you from getting dehydrated during treatment with Nerlynx.

Talk to your doctor if you cannot take loperamide.

4) Have any 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 this medicine. Your doctor will stop your treatment with Nerlynx if your liver tests show severe problems.

Use in Children

Unless you are advised by your doctor that it is necessary to take Nerlynx, you should not take this medicine if you are a child or adolescent under 18. It is not known if NERLYNX is safe and effective in children

Nerlynx with Food and Drink

Do not take grapefruit while you are taking Nerlynx – this includes eating them, drinking the juice or taking a supplement that might

contain them. This is because the grapefruit may interact with Nerlynx and can affect how the medicine works.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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:

- ketoconazole, itraconazole, voriconazole, fluconazole - medicines for fungal infections
- St John's Wort – a herbal product for depression
- carbamazepine, phenytoin – a medicine for seizures
- rifampin - a medicine for tuberculosis (TB)
- erythromycin, clarithromycin – medicines for bacterial infections
- digoxin - a medicine for heart problems
- diltiazem, verapamil – medicines for high blood pressure and chest pain
- Danoprevir and ritonavir, elvitegravir and ritonavir, indinavir and ritonavir, lopinavir and ritonavir – antiviral medicines
- 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' – separate dosing of Nerlynx at least 2 hours before the next dose of the H2 receptor antagonist or 10 hours after you take 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 applies to you (or you are not sure), talk to your doctor or pharmacist before taking Nerlynx.

4. How to use Nerlynx

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

Take the tablets whole with food and a glass of water. Do not crush or dissolve. Do not swallow the desiccant (a drying agent used to keep the tablets from becoming moist).

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

Nerlynx can cause diarrhoea when you first start taking it. Diarrhoea may be severe, causing you to get dehydrated, unless loperamide is taken to prevent or reduce the diarrhoea.

- Start taking loperamide with the first dose of Nerlynx.
- Your doctor will tell you how to take loperamide.
- Keep taking loperamide during the first two months of Nerlynx treatment and then as needed. Your doctor will tell you if you need to keep taking loperamide 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.

How much to use

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The recommended dose of Nerlynx is six 40 mg tablets once a day (a total of 240 mg).

When to use it

Take all the tablets at about the same time each day, preferably in the morning.

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking Nerlynx for as long as directed by your doctor.

The course of treatment is one year.

If you forget to use it

- 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.

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, nurse, or pharmacist.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

5. While You Are Using Nerlynx

Things you must do

Take Nerlynx for as long as your doctor recommends.

Don't stop taking this medicine unless your doctor advises you to.

If you are about to be started on any new medicine, remind your doctor that you are taking Nerlynx.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Use a contraceptive to prevent pregnancy during treatment with Nerlynx and for at least one month after your last dose of Nerlynx.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor or pharmacist. Do not give Nerlynx to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Nerlynx affects you.

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.

6. Side Effects

Tell your doctor as soon as possible if you do not feel well while you are taking Nerlynx.

All medicines may have some unwanted side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of taking this medicine against the benefits they expect it will have for you.

You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately or go to Accident and Emergency Department at your nearest hospital if you get any of the following side effects:

Symptoms of an allergic reaction which may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Diarrhoea

Nerlynx can cause diarrhoea during treatment, which may be reduced or prevented if taken with loperamide or other anti-diarrhoeal medicines. The diarrhoea may be severe, and you may get dehydrated. See the section on ***How to use Nerlynx*** 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 dizziness, weakness or fever 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., pain in the right upper stomach-area (abdomen), yellowing of your skin/whites of your 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.

Tell your doctor if you notice any of the following side effects and they worry you:

Very common side effects – (may affect more than 1 in 10 people):

- 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

The above list includes the most common side effects of your medicine.

This is not a complete list of side effects. For any unexpected effects while taking Nerlynx, contact your doctor immediately.

If you receive Nerlynx and feel any of the symptoms mentioned above during the treatment, your doctor has to be informed. In case you suffer these symptoms, the Nerlynx dose may be stopped or reduced depending on the severity.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of Nerlynx

Storage

Keep your medicine in a cool dry place where the temperature stays 30°C or below. Store in the original container and keep the bottle tightly closed in order to protect from moisture.

Keep out of reach and sight of children.

Disposal

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.

8. Product Description

What it looks like

Red film-coated tablet. The tablet is 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.

An HDPE desiccant canister with 1 g silica gel is enclosed with the tablets in each bottle.

Each bottle contains 180 film-coated tablets.

Ingredients

The active substance is neratinib.

Each film-coated tablet contains neratinib maleate, equivalent to 40 mg neratinib.

Inactive Ingredients

Tablet core: colloidal silicon dioxide, mannitol, microcrystalline cellulose, crospovidone, povidone, magnesium stearate & purified water.

Tablet coating: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide red.

MAL xxxxx

9. Manufacturer and Product Registration Holder

Manufacturer

Excella GmbH & Co. KG
Nurnberger Strasse 12,
D-90537 Feucht, Germany.

Product Registration Holder

Zuellig Pharma Sdn Bhd
No. 15, Persiaran Pasak Bumi,
Seksyen U8, Perindustrian Bukit Jelutong,
40150 Shah Alam, Selangor, Malaysia

Malaysia

10. Date of Revision

06 October 2021

11. Serial Number

NPRA (R1/2) 06102021/196.