1.3.2 Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NERLYNX 40 mg film-coated tablets

Neratinib maleate

Contains sugar alcohol: Each tablet contains 35 mg mannitol.

Read all of this leaflet carefully before you start taking NERLYNX:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NERLYNX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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.
5. How to store NERLYNX.
6. Contents of the pack and other information.

1. What NERLYNX is and what it is used for

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.

NERLYNX is used for patients 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.

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 hypersensitive (allergic) to neratinib maleate or any of the other ingredients of NERLYNX (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 if:

- if you suffer from chronic stomach disorders causing diarrhoea as a symptom,

- if you suffer from kidney problems.
- if you suffer from certain skin disorders.

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:

NERLYNX is not indicated for use in children under the age of 18 years.

Other medicines and NERLYNX:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take NERLYNX if you are currently taking:

- rifampicin (a medicine for tuberculosis),
- carbamazepine, phenobarbital, or phenytoin (medicines for seizures),
- St John's wort (a herbal product for depression).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- 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 (medicine used to treat blood clots),
- digoxin (medicine to treat certain heart problems),
- rosuvastatin (a medicine to treat high cholesterol),
- 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.

If you are taking ranitidine, cimetidine or similar medicines called H_2 receptor antagonists, NERATINIB should be taken 10 hours after the H_2 receptor antagonist dosing and at least 2 hours before the next dose of the H_2 receptor antagonist.

If you are taking any other antacid medicines, the dose of these medicines and NERLYNX should be separated by at least 3 hours.

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 the grapefruit may interact with NERLYNX and affect how NERLYNX works.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking NERLYNX.

Contraception (birth control)

NERLYNX may cause fetal harm. Women who can become pregnant must use an effective method of contraception, including a barrier method (such as using a condom or spermicide):

- while she is taking NERLYNX and,
- for one month after treatment has finished.

Men must use an effective barrier method of contraception (such as using a condom or spermicide):

- while he is taking NERLYNX and,
- for three months after treatment has finished.

Breastfeeding

Talk to your doctor before taking NERLYNX if you are breastfeeding or plan to breastfeed because small amounts of NERLYNX may pass into your breast milk.

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.
It is not always possible to predict to what extent NERLYNX may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which NERLYNX affects you.

3. How to take NERLYNX

Do not share medicines prescribed for you with any other person.

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

Your doctor will tell you how long your treatment with NERLYNX will last. Do not stop treatment early.

If you have the impression that the effect of NERLYNX is too strong or too weak, tell your doctor or pharmacist.

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.

Your doctor will also closely monitor your liver function during treatment with NERLYNX (see section 4, “Possible side effects”). Your doctor will tell you if you need to change the dose of NERLYNX because of your liver function.

If you take more NERLYNX than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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 to take 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 using NERLYNX:

Do not stop taking NERLYNX without talking to your doctor.

4. Possible side effects

NERLYNX can have side effects.

Not all side effects reported for NERLYNX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NERLYNX, please consult your health care provider for advice.

If any of the following happens, stop taking NERLYNX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,

- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to NERLYNX. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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.

Kidney failure

Symptoms include urinating more or less, urine retention – causing swelling in your legs and ankle, fatigue and weakness.

These are all serious side effects. You may need urgent medical attention.

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

Frequent side effects:

- burning sensation during urination and frequent, and urgent need to urinate, (may be symptoms of urinary tract infection),
- decreased appetite,
- dehydration,
- fainting,
- nosebleeds,
- stomach pain, feeling or being sick, low appetite, mild stomach upset,
- dry or inflamed mouth, including blisters or mouth ulcers,
- indigestion,
- rash,
- nail problems including nail splitting or colour change,
- dry skin including cracked skin,
- muscle spasms or cramps,
- fatigue (extreme tiredness, drowsiness),
- weight loss.

Less frequent side effects:

- changes in blood test results (e.g. blood bilirubin increased).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to

SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. To report any adverse reactions to Pierre Fabre (Pty) Ltd, please contact 087 654 2049 or RAZA@pierre-fabre.com or your pharmacist. By reporting side effects, you can help provide more information on the safety of NERLYNX.

5. How to store NERLYNX

- Store at or below 25 °C.
- Keep the bottle tightly closed in order to protect from moisture.
- Store all medicines out of reach of children.
- Do not use NERLYNX 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.
- 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).
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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:

Oval, red film-coated tablet with 'W104' debossed on one side.

Tablet dimensions are 10,5 mm x 4,3 mm with thickness of 3,1 mm.

White, 60 mL high density polyethylene (HDPE) round bottle with child-resistant, polypropylene closure, and foil induction inner seal.

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

Each bottle contains 180 tablets.

Holder of certificate of registration:

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This leaflet was last revised:

25 March 2024

Registration number:

55/26/0541

Date of registration:

31 January 2023.