# nerlynx® (neratinib)

## PATIENT/CARER TREATMENT GUIDE

## HOW TO MANAGE DIARRHOEA WITH NERLYNX®

**This Patient/Carer Treatment Guide is part of the Patient Educational Materials containing:**

- The Patient Information Leaflet, available in the medicine packaging
- The Patient/Carer Treatment Guide
- The Patient Treatment Journal

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the MHRA Yellow Card Scheme at **www.mhra.gov.uk/yellowcard/** or by searching for MHRA Yellow Card in the Google Play or Apple App store. Adverse events should also be reported to Pierre Fabre on **0800 0855292** or **UKdrug.safety@pierre-fabre.com.** By reporting side effects, you can help provide more information on the safety of this medicine.

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Pierre Fabre

# INTRODUCTION

## What is the purpose of this guide?

This guide provides specific guidance on how to recognise and manage diarrhoea if it occurs while taking Nerlynx®. This guidance shall be used alongside the advice of your healthcare professional (HCP) and the Patient Information Leaflet, available in the medicine packaging.

## What is Nerlynx® and what it is used for?

Your doctor has prescribed Nerlynx®, which contains the active substance neratinib. It's an oral anticancer therapy. Nerlynx® is used for patients who have early-stage breast cancer, which:

- is hormone-receptor-positive (HR-positive)

and

- is human epidermal growth factor receptor 2-overexpressed/amplified

and

- has previously been treated with trastuzumab-based therapy that ended less than one year ago

## How to take Nerlynx®?

This medicine must be taken as instructed by your doctor. From time to time your doctor may recommend an adjustment to the dose you are taking.

Check with your doctor or pharmacist if you are not sure.

## How much Nerlynx® to take?

The recommended dose of Nerlynx® is 240mg (6 tablets of 40mg taken once a day).

From time to time, your oncologist may recommend an adjustment to the dose you are taking. Check with your oncologist or pharmacist if you are not sure.

- Take the tablets with food. Tablets should not be crushed or dissolved. 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.

If you get side effects, your doctor may adjust the dose or stop treatment temporarily or permanently.

# HOW TO PREVENT AND MINIMISE THE EFFECTS OF DIARRHOEA

## Diarrhoea during Nerlynx® treatment can be managed by:

1. Using an anti-diarrhoeal medicine prescribed by your doctor.
2. Contacting your healthcare team to see if your Nerlynx® dose needs adjustment.
3. Making dietary changes to minimise diarrhoea.

Your doctor may prescribe anti-diarrhoeal medicines, so that your diarrhoea does not become severe, and to prevent you from getting dehydrated during treatment with Nerlynx®.

## 1. Use of anti-diarrhoeal medicine:

If instructed by your doctor to start an anti-diarrhoeal treatment:

- You should start taking anti-diarrhoeal medicine with the first dose of Nerlynx®
- Your doctor will tell you how to take the anti-diarrhoeal medicine
- You should keep taking anti-diarrhoeal medicine during the first one to two months of Nerlynx® treatment
- Your doctor will tell you if you need to keep taking anti-diarrhoeal 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

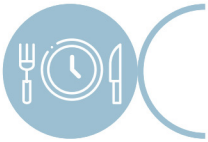
## 2. When to contact your healthcare team to see if your Nerlynx® dose needs adjustment:

- You are having diarrhoea that does not go away → they can advise how to control your diarrhoea
- You feel dizzy or weak from diarrhoea or have a fever → go to the hospital immediately
- You are having constipation → they can advise how to adapt anti-diarrhoeal treatment. If your doctor is not available, go to the hospital immediately.

## 3. Dietary changes to minimise diarrhoea:

The following tips may help you minimise diarrhoea, but always talk to your doctor, pharmacist or nurse before making any changes to your diet.

### THINGS TO DO:



**Eat small, frequent meals**



**Drink more clear liquids**

Try to drink ~2L of clear fluids a day. These include water, broth, weak decaffeinated tea, and clear juices. Discuss with your doctor if you have been advised to restrict your fluid intake for medical reasons.



**Choose foods that are easy to digest**

(low-residue diet).

These include bananas, rice, apple sauce, and toast.

### THINGS TO AVOID:



**Medicines such as laxatives or stool softeners**



**Caffeine, alcohol, dairy, fat, fibre, orange juice, grapefruit juice, pomegranate juice, prune juice, and spicy foods**

# SIDE EFFECTS

## What is the main side effect when taking Nerlynx®?

- Diarrhoea is a very common side effect of Nerlynx®
- It generally occurs early during the first or second week of treatment with Nerlynx® and may be recurrent
- It was reported that a single episode of diarrhoea may last a few days
- Diarrhoea can be serious and might lead to hospitalisation

In this guide, we provide information on how to prevent diarrhoea and how to manage it, should it occur.

## Signs and symptoms:

Diarrhoea involves more frequent than usual, loose, or watery bowel movements (stools). Your "baseline" is the usual number of stools you have in a day.

You should record the number of bowel movements you have each day in your Patient Treatment Journal, starting the week before you start taking Nerlynx®.

## Talk to your doctor if:

- You are having diarrhoea that does not go away → they can advise how to control your diarrhoea. If your doctor is not available, go to the hospital immediately
- You feel dizzy or weak from diarrhoea or have a fever → go to the hospital immediately

## Risks and consequences of diarrhoea

Although uncomfortable, mild diarrhoea usually does not cause serious problems.

Severe diarrhoea, however, can cause dehydration and electrolyte imbalances. This happens when the body loses too much water. It may also cause other health problems (such as renal disorders).

To avoid dehydration, take steps to prevent diarrhoea as instructed by your doctor and ensure that your fluid intake is adequate.

## Use your Patient Treatment Journal:

This will help your healthcare team to determine if and how to adjust your medication, should diarrhoea occur.

Note the average number of stools you had per day in the week before you start Nerlynx® according to your memory, as precisely as possible, in order not to delay the start of the treatment.

When you start taking Nerlynx®, record your daily number of stools along with your body weight to review with your healthcare team.

It is very important that you take the completed Patient Treatment Journal to each visit with your HCP, in order to assist in effectively managing any diarrhoea you may experience.

The Patient Treatment Journal covers the first two months of the treatment, since the diarrhoea occurs most frequently in this treatment period. Ask your healthcare team if you need to be provided with an additional Patient Treatment Journal material.

## Other side effects:

In addition to diarrhoea, you may experience other adverse effects with Nerlynx®. See the Patient information Leaflet, available in the medicine packaging.

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