

INTRODUCTION

What is the purpose of this brochure?

This brochure provides specific guidance on how to recognise and manage diarrhoea, if it occurs while taking Nerlynx. This guidance should be used alongside the advice of your oncologist.

Please also read the Patient Information Leaflet, available in the medicine packaging or online (<https://www.medicines.org.uk/emc/product/10477/pil>) or via Pierre Fabre Medical Information Department on **0800 085 5292** or via email medicalinformation@pierre-fabre.co.uk

What is Nerlynx and what is it used for?

Your oncologist has prescribed Nerlynx, which contains the active substance neratinib. Nerlynx is used for patients who have early stage breast cancer:

- Which is human epidermal growth factor receptor 2-positive (HER2-positive)
- Which is hormone receptor-positive (HR-positive)
- For which previous treatment with another medicine called 'trastuzumab' was completed less than one year ago

How to take Nerlynx

This medicine must be taken as instructed by your oncologist.

Recommended dosage of Nerlynx is 6 tablets once a day (a total of 240 mg).

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 preferably in the morning
- Do not crush or dissolve
- Do not ingest the silica gel supplied with your medicine; this is provided only to keep your medicine dry
- Swallow the tablets whole with water
- **You will need to take an anti-diarrhoeal medicine when you start taking Nerlynx**

The course of treatment is one year.

SIDE EFFECTS

What is the main side effect when taking Nerlynx?

- Diarrhoea is a very common side effect of Nerlynx and anti-diarrhoeal medicines should be taken to prevent or reduce diarrhoea.
- Diarrhoea usually happens early in treatment with Nerlynx, in the first month, and may be recurrent
- Diarrhoea may be severe, causing you to get dehydrated
- Diarrhoea can be serious and might lead to hospitalisation

In this brochure 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).

Risks and consequences of diarrhoea

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

But severe diarrhoea can cause dehydration and electrolyte imbalances. This happens when the body loses too much water.

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

Completing your Patient Treatment Journal

This will help your oncologist to determine how to adjust your medication, should diarrhoea occur.

In the week before you start Nerlynx, note the number of bowel movements you have per day. This is your baseline.

When you start taking Nerlynx, record your number of bowel movements each day along with your body weight to review with your oncologist.

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

Other side effects

In addition to diarrhoea, you may experience other side effects with Nerlynx. Please read the Patient Information Leaflet fully.

If you get any side effects, talk to your oncologist, nurse or pharmacist. By reporting side effects you can help provide more information on the safety of this medicine.

▼ 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. If you get any side effects, talk to your oncologist or pharmacist. You can also report side effects directly via 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 and/or to the Pharmacovigilance Department of Pierre Fabre Limited on **0800 0855292** or via ukdrug.safety@pierre-fabre.com.