

The ROYAL MARSDEN

NHS Foundation Trust

Neratinib treatment in advanced or metastatic breast cancer

Breast Unit

Patient Information



NHS

Neratinib treatment in advanced or metastatic breast cancer

Your doctor has recommended treatment with neratinib (Nerlynx). This is a tablet known as a small molecule inhibitor of HER2, used in the treatment of patients with advanced/metastatic HER2 positive breast cancer. It is not currently licensed in the UK, but is being supplied free of charge by the drug company for patients whose doctors think they may benefit from it.

It is usually, but not always, given with capecitabine, an oral chemotherapy tablet (please see the Macmillan website which has further details on capecitabine). The aim of treatment is to shrink the cancer and improve symptom control, not cure. Treatment may be continued at the discretion of your medical team for as long as the treatment is working. These treatments can only be prescribed by your oncology doctor and we will usually give you a supply each time you attend for review and blood tests.

How to take neratinib

Neratinib tablets are taken orally, once a day. The tablets should be taken with food at the same time each day. The neratinib dose may change depending on the side effects experienced.

If you take an antacid medicine such as Gaviscon®, take neratinib three hours after the antacid medicine. If you take a H2-receptor blocker such as ranitidine, then neratinib should be taken at least two hours before or 10 hours after you take these medicines. Proton pump inhibitors, such as lansoprazole or omeprazole, should not be taken with neratinib.

If you miss a dose of neratinib, skip that dose and take your next dose at your regular scheduled time.

If you take too many tablets, call The Royal Marsden Macmillan Hotline immediately or go to the local Accident and Emergency department, taking the medication packet with you.

Tablets should be stored at room temperature.

What to avoid when taking neratinib

You must avoid products containing grapefruit. There are also some medications which can be affected by taking neratinib. Please tell your doctor about all the medications that you are currently taking and discuss any new medications with your doctor before you start taking them with neratinib.

Side effects of neratinib

Diarrhoea – diarrhoea is a very common side effect and can also be severe.

Diarrhoea can cause you to lose salts and fluids leading to dehydration. Dehydration symptoms include thirst, decreased urine volume, abnormally dark urine, unexplained tiredness or fatigue, headache, dry mouth, dry skin, and dizziness when standing. Dehydration can cause low blood pressure and kidney injury.

It may be necessary to reduce the dose of neratinib or to temporarily/permanently stop treatment if the diarrhoea is severe.

We will prescribe you supportive medications (loperamide and budesonide tablets) to help prevent, or reduce diarrhoea while on neratinib:

- **Loperamide**

- You should start taking loperamide with your first dose of neratinib
- Keep taking loperamide regularly during the first two months (56 days) of neratinib treatment
- After two months (56 days) of treatment with neratinib, follow your healthcare provider's instructions about taking loperamide as needed to control the diarrhoea
- Please refer to the loperamide patient information leaflet supplied with the medication for side effects.

- **Budesonide**

- You should start taking budesonide with your first dose of neratinib

- Keep taking budesonide regularly during the first month (28 days) of neratinib treatment
- Please refer to the budesonide patient information leaflet supplied with the medication for side effects.

Contact The Royal Marsden Macmillan Hotline if you have more than two loose stools in a day, despite using loperamide, or if you feel weak, dizzy or feverish.

Other side effects

Very common ($\geq 1/10$) [occurs in 10 or more people in 100]

- Nausea
- Abdominal pain (includes upper/lower abdominal pain, abdominal discomfort, abdominal distension)
- Vomiting
- Pain, redness, swelling or sores in the mouth, and/or throat
- Fatigue
- Decreased appetite
- Muscle spasms
- Rash (includes red, flat, patchy rashes or raised small bumps which may cause itchiness and may occur in more than one area of the body, and/or may contain fluid or pus)
- Dry skin including deep skin cracking and/or dry mouth.

Common ($\geq 1/100$ and $< 1/10$) [occurs in 9 or less people in 100]

- Increase in alanine aminotransferase (an increase in an enzyme that measures the function of the liver)
- Increase in aspartate aminotransferase (an increase in an enzyme that measures the function of the liver)
- Dyspepsia (indigestion)
- Urinary tract infection
- Weight loss
- Dehydration
- Nose bleed
- Nail disorder (inflammation/infection, breaking or discolouration).

Uncommon [occurs in less than 9 people in 1000]

Though uncommon, the side effects listed below are important to be aware of as they can be life-threatening if not treated rapidly. Call The Royal Marsden Macmillan Hotline immediately if you develop any of the symptoms below:

- **Severe liver damage:** This may cause severe changes in liver function tests, which may indicate severe liver damage. If you experience multiple loose bowel movements in a day or any worsening of fatigue, nausea, vomiting, jaundice (skin or eyes turning yellow), abdominal pain or tenderness, fever or rash, contact us immediately.
- **Interstitial lung disease:** Rarely, patients treated with neratinib experience pneumonitis (inflammation and scarring of the lungs). If you feel short of breath or develop a cough, please contact us immediately.

Risks to unborn children

It is not known whether neratinib may cause side effects to pregnant women, to an unborn child (an embryo or a foetus), or to children being breastfed. Because of these unknown risks, if you are pregnant or trying to become pregnant you should not take neratinib. If you are breastfeeding, you should not take neratinib.

Whilst taking neratinib, patients must use a reliable method of contraception. Your doctor can discuss this further with you. After your last dose of the neratinib you should continue to use contraception for 28 days.

If you miss a period or think you might be pregnant during your treatment of neratinib, you should tell your doctor immediately.

The effects of neratinib on an unborn child (embryo or foetus) fathered by a man taking neratinib are unknown. Men with partners of childbearing potential should use a reliable method of contraception throughout treatment of neratinib and for three months after the last dose of neratinib.

If you have any further questions regarding neratinib treatment, please discuss with your doctor.

Alternatively, please call:

The Royal Marsden Macmillan Hotline: 020 8915 6899
(available 24 hours a day, 7 days a week)

Notes and questions

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References

This booklet is evidence based wherever the appropriate evidence is available, and represents an accumulation of expert opinion and professional interpretation.

Details of the references used in writing this booklet are available on request from:

The Royal Marsden Help Centre

Telephone: Chelsea 020 7811 8438 / 020 7808 2083

Sutton 020 8661 3759 / 3951

Email: patientcentre@rmh.nhs.uk

No conflicts of interest were declared in the production of this booklet.

Should you require information in an alternative format, please contact The Royal Marsden Help Centre.

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