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Nerlynx (*neratinib*)

An overview of Nerlynx and why it is authorised in the EU

What is Nerlynx and what is it used for?

Nerlynx is a breast cancer medicine used to reduce the risk of the disease coming back in patients with early breast cancer who have had surgery. It is given following treatment with trastuzumab (another medicine used for the same purpose).

It is intended for use only in breast cancers that produce high levels of a protein called HER2, which helps cells to divide and grow (HER2-positive breast cancer), and that also have receptors (targets) for the female sex hormones (hormone-receptor positive breast cancer).

How is Nerlynx used?

Nerlynx treatment should be started and supervised by a doctor experienced in giving cancer medicines and can only be obtained with a prescription.

The medicine is available as tablets (40 mg). The recommended dose is 6 tablets (240 mg) once a day with food, preferably in the morning. Treatment should be started within a year of finishing treatment with trastuzumab, and is given for 1 year. The doctor may reduce the dose or stop treatment if a patient has severe side effects, including diarrhoea. The doctor may also modify the dose if Nerlynx is given with certain other medicines. Patients are given treatment to prevent diarrhoea when starting Nerlynx.

For more information about using Nerlynx, see the package leaflet or contact your doctor or pharmacist.

How does Nerlynx work?

The active substance in Nerlynx, neratinib, is a type of cancer medicine called a tyrosine kinase inhibitor. It attaches to the HER2 protein on the cancer cells, and so blocks its action. Because HER2 helps cancer cells to grow and divide, blocking it helps to stop these cells growing and prevents the cancer from coming back.

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What benefits of Nerlynx have been shown in studies?

Nerlynx has been shown to be more effective than placebo (a dummy treatment) at preventing the cancer from coming back in one main study involving 2,840 women with HER2-positive early breast cancer who had already received trastuzumab.

Around 94% of the women given a year's treatment with Nerlynx lived for 1 further year after stopping Nerlynx without their cancer coming back versus 92% of those given placebo. When only women with hormone-receptor positive cancer were considered, about 95% of those given Nerlynx lived another year without the cancer coming back versus 91% of those given placebo.

What are the risks associated with Nerlynx?

The most common side effect with Nerlynx is diarrhoea, which affects nearly all patients. Other common side effects (which may affect more than 1 in 10 people) are nausea (feeling sick), vomiting, tiredness, belly pain, rash, decreased appetite, stomatitis (sore, inflamed mouth), and muscle spasms. The most common serious side effects are diarrhoea and vomiting. For the full list of side effects of Nerlynx, see the package leaflet.

Nerlynx must not be used in patients with severely reduced liver function. It must also not be used with certain medicines that affect the way Nerlynx is broken down in the body. For the full list of restrictions, see the package leaflet.

Why is Nerlynx authorised in the EU?

The European Medicines Agency considered that Nerlynx had been shown to be of benefit in women with HER2-positive early breast cancer, and that this benefit seemed to be mainly in women with hormone-receptor positive disease.

Although the side effects, particularly diarrhoea, can be severe and lead to treatment being stopped, there would be patients with HER2-positive, hormone-receptor positive early breast cancer for whom treatment with Nerlynx after surgery and trastuzumab would be a reasonable option. The Agency therefore decided that Nerlynx's benefits are greater than its risks in this group and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Nerlynx?

The company that markets Nerlynx will provide a guide for healthcare professionals who prescribe or dispense the medicine, and educational material for patients and carers. These materials will explain the effects of Nerlynx on the gut, such as diarrhoea, and how to manage them, and will give advice on the need for patients to tell their healthcare professionals of side effects.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nerlynx have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Nerlynx are continuously monitored. Side effects reported with Nerlynx are carefully evaluated and any necessary action taken to protect patients.

Other information about Nerlynx

Nerlynx received a marketing authorisation valid throughout the EU on 31 August 2018.

Further information on Nerlynx can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.