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Kisqali (*ribociclib*)

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

What is Kisqali and what is it used for?

Kisqali is a medicine used to treat early breast cancer at high risk of coming back and breast cancer that is locally advanced (has spread nearby) or metastatic (has spread to other parts of the body). It can only be used when the cancer cells have receptors (targets) for certain sex hormones on their surface (HR-positive) and do not have large quantities of another receptor called HER2 (HER2-negative).

Kisqali should always be used in combination with hormonal treatment that reduces the effect of oestrogen: an aromatase inhibitor (which reduces oestrogen levels) in early breast cancer, or either fulvestrant (which blocks oestrogen receptors) or an aromatase inhibitor in advanced breast cancer.

If Kisqali is used in women before the menopause or around the time of menopause (pre-menopausal or peri-menopausal), or in men, it should also be given in combination with an LHRH inhibitor (a medicine that blocks the effects of luteinising hormone-releasing hormone).

Kisqali contains the active substance ribociclib.

How is Kisqali used?

Kisqali can only be obtained with a prescription and treatment should be started by a doctor experienced in the use of cancer treatments.

Kisqali is available as tablets to take by mouth once daily for 21 days, followed by a 7-day break to complete a 28-day treatment course. In patients with early breast cancer, treatment courses are continued for three years or until the cancer comes back, unless the side effects become unacceptable. In patients with advanced or metastatic breast cancer, treatment courses should continue as long as the medicine continues to work and the patient does not get unacceptable side effects.

If the patient gets severe side effects, the doctor may reduce the dose of Kisqali, or interrupt or stop treatment with the medicine.

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

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How does Kisqali work?

The active substance in Kisqali, ribociclib, blocks the activity of enzymes known as cyclin-dependent kinases (CDK) 4 and 6, which are important for regulating the way cells grow and divide. By blocking CDK4 and CDK6, Kisqali slows the growth of HR-positive breast cancer cells.

What benefits of Kisqali have been shown in studies?

Early breast cancer

Kisqali was found effective in one main study involving 5,101 patients, including 20 men, with HR-positive, HER2-negative early breast cancer. Patients in the study received either Kisqali plus an aromatase inhibitor (letrozole or anastrozole) or an aromatase inhibitor on its own.

The study showed that three years after starting treatment, around 91% of patients taking Kisqali with an aromatase inhibitor were alive and did not experienced recurrence of disease in the form of spreading elsewhere in the body or locally invasive disease (invasive disease-free survival), compared with 88% of patients treated with an aromatase inhibitor alone.

Advanced or metastatic breast cancer

Kisqali was found effective in 3 main studies in women with HR-positive, HER2-negative advanced breast cancer.

In one main study involving 668 post-menopausal women with advanced breast cancer that had not been treated previously, patients received either Kisqali with letrozole or placebo (a dummy treatment) with letrozole. Women taking Kisqali with letrozole lived on average 25.3 months without the disease getting worse compared with 16.0 months in those taking placebo with letrozole.

Another main study involved 495 pre-menopausal women with advanced breast cancer that had not been treated previously and who received goserelin (an LHRH inhibitor) plus letrozole or anastrozole (aromatase inhibitors) combined with either Kisqali or placebo. Women taking Kisqali lived on average for 27.5 months without their disease getting worse compared with 13.8 months in those taking placebo.

A further study involved 726 post-menopausal women who had either not been treated previously or had received only hormonal treatment (to reduce the effects of oestrogen). Patients received fulvestrant either with Kisqali or with placebo. Patients taking Kisqali with fulvestrant lived on average for 20.6 months without their disease getting worse compared with 12.8 months for those receiving placebo with fulvestrant.

What are the risks associated with Kisqali?

For the full list of side effects and restrictions of Kisqali, see the package leaflet.

When used to treat early breast cancer, the most common side effects with Kisqali (which may affect more than 1 in 5 people) include low levels of white blood cells, infections, nausea (feeling sick), headache, tiredness and abnormal blood tests for liver function. The most common severe side effects (which may affect more than 1 in 50 people) include low levels of red and white blood cells and abnormal liver function tests.

When used in the treatment of advanced breast cancer, the most common side effects with Kisqali (which may affect more than 1 in 5 people) include infections, low levels of white and red blood cells, headache, cough, nausea, vomiting, diarrhoea, constipation, tiredness, back pain, hair loss, rash and abnormal liver function tests.

The most common severe side effects (which may affect more than 1 in 50 people) include infections, low levels of red and white blood cells, vomiting, tiredness, back pain, abnormal blood tests for liver function and low levels of phosphate in the blood (hypophosphataemia).

Kisqali must not be used in patients who are hypersensitive (allergic) to any of the ingredients or to peanuts or soya.

Why is Kisqali authorised in the EU?

Kisqali used with an aromatase inhibitor was shown to be effective in the treatment of early HR-positive, HER2-negative breast cancer.

Kisqali used with an aromatase inhibitor or fulvestrant increased the time it took for the disease to get worse in women with HR-positive and HER2-negative breast cancer that was locally advanced or metastatic. Pre-menopausal and peri-menopausal women with advanced breast cancer also lived longer without the cancer getting worse when Kisqali was combined with an aromatase inhibitor plus a medicine to block LHRH. The European Medicines Agency considered that Kisqali's pattern of side effects has been well established and the side effects are manageable.

The Agency therefore decided that Kisqali's benefits are greater than its risks and it can be authorised for use in the EU.

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

To further evaluate the benefits of Kisqali in the treatment of patients with HR-positive, HER2-negative early breast cancer, the company that markets the medicine will continue to follow up patients included in the main study for 5 years and submit the results of this study to the Agency.

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

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

Other information about Kisqali

Kisqali received a marketing authorisation valid throughout the EU on 22 August 2017.

Further information on Kisqali can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/kisqali.

This overview was last updated in 11-2024.