EMA/540758/2017
EMEA/H/C/004213

EPAR summary for the public

Kisqali

ribociclib

This is a summary of the European public assessment report (EPAR) for Kisqali. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Kisqali.

For practical information about using Kisqali, patients should read the package leaflet or contact their doctor or pharmacist.

What is Kisqali and what is it used for?

Kisqali is a cancer medicine used to treat advanced or metastatic breast cancer (cancer that has spread to other parts of the body) in postmenopausal women.

Kisqali can only be used when the cancer cells have receptors for certain hormones on their surface (HR-positive) and do not have large quantities of another receptor called HER2 (HER2-negative). Kisqali is used with an aromatase inhibitor (a cancer medicine that reduces oestrogen).

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 200-mg tablets. The usual recommended dose is 3 tablets (600 mg) once daily for 21 days followed by a 7-day break to complete a 28-day treatment course. The patient should take the tablets at around the same time each day, usually in the morning. Treatment courses should be continued for 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.

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For further information, see the package leaflet.

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?

Kisqali was found to be effective in one main study involving 668 women with HR-positive, HER2-negative breast cancer. The mean measure of effectiveness was how long the women lived without their disease getting worse (progression-free survival).

In this study, women received either Kisqali with letrozole (an aromatase inhibitor) 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.

What are the risks associated with Kisqali?

The most common side effects with Kisqali (which may affect more than 1 in 5 people) are low levels of white blood cells, headache, back pain, nausea (feeling sick), vomiting, diarrhoea, constipation, tiredness, hair loss and rash.

The most common severe side effects with Kisqali (which may affect more than 1 in 50 people) are low levels of white blood cells, nausea, 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.

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

Why is Kisqali approved?

The European Medicines Agency decided that Kisqali's benefits are greater than its risks and recommended that it be approved for use in the EU. Kisqali used with an aromatase inhibitor increased the time it took for the disease to get worse in postmenopausal women with HR-positive and HER2-negative breast cancer that is advanced or metastatic. The Agency considered that Kisqali's pattern of side effects has been fairly well established and the side effects appear manageable.

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

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

Other information about Kisqali

The European Commission granted a marketing authorisation valid throughout the European Union for Kisqali on 22 August 2017.

The full EPAR for Kisqali can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Kisqali, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2017.