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EPAR summary for the public

Kisplyx

lenvatinib

This is a summary of the European public assessment report (EPAR) for Kisplyx. 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 Kisplyx.

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

What is Kisplyx and what is it used for?

Kisplyx is a cancer medicine used to treat adults with advanced renal cell carcinoma (a type of kidney cancer) who have been previously treated with a type of cancer medicine called a 'vascular endothelial growth factor (VEGF) inhibitor'. Kisplyx is used together with another cancer medicine called everolimus.

Kisplyx contains the active substance lenvatinib.

How is Kisplyx used?

Kisplyx can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in using cancer medicines.

Kisplyx is available as capsules (4 mg and 10 mg). The recommended dose is 18 mg (made up of one 10 mg capsule and two 4 mg capsules) once a day at the same time each day in combination with 5 mg of everolimus once a day. The dose of Kisplyx may need to be reduced or treatment stopped temporarily if certain side effects occur. Treatment is given for as long as the patient benefits from it or until side effects become unacceptable. The dose of Kisplyx should be decreased in patients with severely reduced kidney or liver function.

For further information, see the package leaflets for Kisplyx and the medicine containing everolimus.

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How does Kisplyx work?

The active substance in Kisplyx, lenvatinib, is a 'tyrosine-kinase inhibitor'. This means that it blocks the activity of enzymes known as tyrosine kinases. These enzymes can be found in certain receptors (such as VEGF, FGFR, PDGF, KIT and RET receptors) in cancer cells, where they activate several processes including cell division and the growth of new blood vessels. By blocking these enzymes, lenvatinib can block the formation of new blood vessels, cutting off the blood supply that keeps cancer cells growing, and reduce the growth of the cancer.

What benefits of Kisplyx have been shown in studies?

Kisplyx has been investigated in one main study involving 153 adults with advanced renal cell carcinoma that had got worse despite treatment with a VEGF inhibitor. The study compared the combination of Kisplyx and everolimus with Kisplyx or everolimus alone. The main measure of effectiveness was how long the patients lived without their disease getting worse (progression-free survival). Patients who took the combination of Kisplyx and everolimus lived for an average of 14.6 months without their disease getting worse, compared with 7.4 months for the patients who took Kisplyx alone and 5.5 months for the patients who took everolimus alone.

What are the risks associated with Kisplyx?

The most common side effects with Kisplyx, when used in combination with everolimus or alone and which may affect more than 3 in 10 people, are diarrhoea, high blood pressure, tiredness, loss of appetite and weight, vomiting, nausea (feeling sick), proteinuria (protein in the urine), stomatitis (inflammation of the lining of the mouth), headache, dysphonia (speech disturbances), palmar-plantar erythrodysaesthesia syndrome (hand-foot syndrome, which involves rash and numbness on the palms and soles), peripheral oedema (swelling, especially of the ankles and feet) and hypercholesterolemia (high levels of cholesterol [type of fat] in the blood).

The most important serious side effects are kidney failure and reduced kidney function; problems with the heart and circulation such as heart failure and blood clots in the arteries leading to stroke or heart attack; bleeding in the brain or bleeding of a tumour within the skull; a syndrome known as 'posterior reversible encephalopathy syndrome' characterised by headache, confusion, fits and loss of vision; and liver failure. For the full list of all side effects reported with Kisplyx, see the package leaflet. For the list of all side effects reported with everolimus, see the package leaflet of the medicine containing everolimus.

Kisplyx must not be taken by breastfeeding women. For the full list of restrictions, see the package leaflet.

Why is Kisplyx approved?

Previously treated patients with advanced renal cell carcinoma have poor outcomes and a high unmet medical need. Kisplyx, used in combination with everolimus, was shown to significantly improve the time these patients lived without their disease getting worse. The safety of Kisplyx used in combination with everolimus is similar to that of these medicines when used individually, and side effects are considered manageable. The Agency's Committee for Medicinal Products for Human Use (CHMP) therefore decided that Kisplyx's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Kisplyx

The European Commission granted a marketing authorisation valid throughout the European Union for Kisplyx on 25 August 2016.

The full EPAR for Kisplyx 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 Kisplyx, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2016.