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EPAR summary for the public

Cabometyx

cabozantinib

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

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

What is Cabometyx and what is it used for?

Cabometyx 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 'vascular endothelial growth factor (VEGF) inhibitor'.

Cabometyx contains the active substance cabozantinib.

How is Cabometyx used?

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

Cabometyx is available as tablets (20, 40 and 60 mg). The recommended dose is 60 mg once a day. Patients should not eat for at least two hours before and one hour after taking Cabometyx. The dose may need to be reduced or treatment stopped temporarily if serious or unacceptable side effects occur. Treatment is continued for as long as the patient benefits from it or until side effects become unacceptable. For further information, see the package leaflet.

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How does Cabometyx work?

The active substance in Cabometyx, cabozantinib, 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, MET, AXL and RET receptors) in cancer cells, where they activate several processes including cell division and the growth of new blood vessels to supply the cancer. By blocking the activity of these enzymes in cancer cells, the medicine reduces the growth and spread of the cancer.

What benefits of Cabometyx have been shown in studies?

Cabometyx has been investigated in one main study involving 658 adults with advanced renal cell carcinoma that had got worse despite treatment with a VEGF inhibitor. In the study, Cabometyx was compared with the cancer medicine everolimus. Results showed that Cabometyx is effective at prolonging the time patients lived without their disease getting worse (progression-free survival): patients treated with Cabometyx lived for an average of 7.4 months without their disease getting worse compared with 3.8 months in patients treated with everolimus. In addition, preliminary results indicated that patients treated with Cabometyx lived overall longer than patients treated with everolimus (an average of 21.4 months compared with 16.5 months).

What are the risks associated with Cabometyx?

The most common side effects with Cabometyx (seen in at least 1 in 4 people) are diarrhoea, tiredness, nausea (feeling sick), loss of appetite, palmar-plantar erythrodysaesthesia syndrome (hand-foot syndrome, which involves rash and numbness on the palms and soles), high blood pressure, vomiting, loss of weight and constipation. The most common serious side effects are abdominal (belly) pain, pleural effusion (build-up of fluid around the lungs), diarrhoea and nausea.

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

Why is Cabometyx approved?

Previously treated patients with advanced renal cell carcinoma have poor outcomes and a high unmet medical need. Cabometyx was shown to significantly improve the time these patients lived without their disease getting worse. Early results also indicated that Cabometyx helped patients to live longer. The side effects of Cabometyx are similar to other tyrosine kinase inhibitors used in renal cell carcinoma, and they are considered manageable. The European Medicines Agency therefore decided that Cabometyx'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 Cabometyx?

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

Other information about Cabometyx

The European Commission granted a marketing authorisation valid throughout the European Union for Cabometyx on 9 September 2016.

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

This summary was last updated in 12-2017