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EPAR summary for the public

Inlyta

axitinib

This is a summary of the European public assessment report (EPAR) for Inlyta. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Inlyta.

What is Inlyta?

Inlyta is a medicine that contains the active substance axitinib. It is available as tablets (1, 3, 5 and 7 mg).

What is Inlyta used for?

Inlyta is used to treat adults with advanced renal cell carcinoma, a type of kidney cancer. 'Advanced' means that the cancer has started to spread. Inlyta is used when treatment with Sutent (sunitinib) or 'cytokines' (other cancer medicines) has failed.

The medicine can only be obtained with a prescription.

How is Inlyta used?

Treatment with Inlyta should be started by doctors who have experience in using cancer medicines.

The recommended starting dose is 5 mg twice a day, taken approximately 12 hours apart. The dose can be adjusted according to the patient's response. In patients who tolerate the 5 mg dose well, who do not have high blood pressure and are not taking blood pressure medicines, the dose may be increased first to 7 mg then to a maximum of 10 mg twice a day. It may be necessary to reduce the dose or interrupt treatment to manage certain side effects. In patients taking certain other medicines, the doctor may need to adjust the dose of Inlyta.

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Patients with moderately reduced liver function should receive a starting dose of 2 mg twice a day. Inlyta should not be used in patients with severely reduced liver function.

How does Inlyta work?

The active substance in Inlyta, axitinib, works by blocking some enzymes known as tyrosine kinases that are found in 'vascular endothelial growth factor' (VEGF) receptors on the surface of cancer cells. VEGF receptors are involved in the growth and spread of cancer cells and in the development of blood vessels that supply the tumours. By blocking these receptors, Inlyta helps to reduce the growth and spread of the cancer and cut off the blood supply that keeps the cancer cells growing.

How has Inlyta been studied?

Inlyta has been compared with sorafenib (another cancer medicine) in one main study involving 723 patients with advanced renal cell carcinoma whose previous treatment with other cancer medicines such as sunitinib or cytokines had failed. The main measure of effectiveness was how long the patients lived without their tumour getting worse.

What benefit has Inlyta shown during the studies?

Inlyta was more effective than sorafenib in treating advanced renal cell carcinoma. Patients taking Inlyta lived for an average of 6.7 months without the disease getting worse, compared with 4.7 months in the patients taking sorafenib. Effects were better for those patients who were previously treated with cytokines rather than sunitinib.

What is the risk associated with Inlyta?

The most common side effects with Inlyta (seen in more than 20% of patients) are diarrhoea, hypertension (high blood pressure), fatigue (tiredness), dysphonia (speech disturbance), nausea (feeling sick), vomiting, decreased appetite, weight loss, palmar-plantar erythrodysaesthesia syndrome (rash and numbness on the palms of the hands and soles of the feet), haemorrhage (bleeding), hypothyroidism (an underactive thyroid gland), protein in urine, cough and constipation.

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

Why has Inlyta been approved?

The CHMP concluded that the effectiveness of Inlyta in treating patients with advanced renal cell carcinoma for whom treatment with Sutent or a cytokine failed has been demonstrated. Regarding its safety, the side effects of the medicine are similar to other medicines in the same class and are considered to be acceptable and manageable. The CHMP therefore decided that Inlyta's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Inlyta is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Inlyta, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Inlyta

The European Commission granted a marketing authorisation valid throughout the European Union for Inlyta on 3 September 2012.

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

This summary was last updated in 06-2015.