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EPAR summary for the public

Sutent

sunitinib

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

What is Sutent?

Sutent is a medicine that contains the active substance sunitinib. It is available as capsules (12.5 mg, 25 mg, 37.5 mg and 50 mg).

What is Sutent used for?

Sutent is used to treat adults with the following types of cancer:

- gastrointestinal stromal tumour (GIST), a type of cancer of the stomach and bowel where there is uncontrolled growth of cells in the supporting tissues of these organs. Sutent is used in patients with GISTs that cannot be removed with surgery or have spread to other parts of the body. It is used after treatment with imatinib (another cancer medicine) has failed;
- metastatic renal cell carcinoma, a type of kidney cancer, that has spread to other parts of the body;
- pancreatic neuroendocrine tumours (tumours of the hormone-producing cells in the pancreas) that have spread or cannot be removed with surgery. Sutent is used if the disease is getting worse and the tumour cells are well-differentiated (similar to normal cells in the pancreas).

The medicine can only be obtained with a prescription.



How is Sutent used?

Treatment with Sutent should be started by doctors who have experience in administering cancer medicines.

For GIST and metastatic renal cell carcinoma, Sutent is given in six-week cycles, at a dose of 50 mg once a day for four weeks, followed by a two-week 'rest period'. The dose can be adjusted according to the patient's response to the treatment, but should be kept within the range of 25 to 75 mg.

For pancreatic neuroendocrine tumours, Sutent is given at a dose of 37.5 mg once a day without a rest period. This dose may also be adjusted.

How does Sutent work?

The active substance in Sutent, sunitinib, is a protein kinase inhibitor. This means that it blocks some specific enzymes known as protein kinases. These enzymes can be found in some receptors at the surface of cancer cells, where they are involved in the growth and spread of cancer cells and in the blood vessels that supply the tumours, where they are involved in the development of new blood vessels. By blocking these enzymes, Sutent can reduce the growth and spread of the cancer and cut off the blood supply that keeps cancer cells growing.

How has Sutent been studied?

Sutent was compared with placebo (a dummy treatment) in 312 patients with GIST whose previous treatment with imatinib had failed and in 171 patients with worsening pancreatic neuroendocrine tumours that could not be removed with surgery. Sutent was also compared with another cancer medicine, interferon alfa, in 750 patients with metastatic renal cell carcinoma whose cancer had not been treated before.

The main measure of effectiveness in all of the studies was how long the patients lived without their tumours getting worse.

What benefit has Sutent shown during the studies?

Sutent was more effective than placebo in treating GIST and pancreatic neuroendocrine tumours. Patients with GIST taking Sutent lived for an average of 26.6 weeks without the disease getting worse, compared with 6.4 weeks in the patients taking placebo. For pancreatic neuroendocrine tumours the figures were 11.4 months in the Sutent group and 5.5 months in the placebo group.

In metastatic renal cell carcinoma, patients taking Sutent lived for an average of 47.3 weeks without their disease worsening, compared with 22.0 weeks in the patients receiving interferon alfa.

What is the risk associated with Sutent?

The most common side effects with Sutent (seen in more than 1 in 10 patients) include fatigue (tiredness), gastrointestinal disorders (such as diarrhoea, feeling sick, inflammation of the lining of the mouth, indigestion and vomiting), respiratory (such as shortness of breath and cough) and skin disorders (such as skin discoloration, dryness of the skin and rash), hair color changes, dysgeusia (taste disturbances), epistaxis (nosebleeds), loss of appetite, hypertension (high blood pressure), palmar-plantar erythrodysesthesia syndrome (rash and numbness on the palms and soles), hypothyroidism (an underactive thyroid gland), insomnia (difficulty falling and staying asleep), dizziness, headache, arthralgia (joint pain), neutropenia (low levels of neutrophils, a type of white

blood cell), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts), and leucopenia (low white blood cell counts).

The most serious side effects reported with Sutent include heart and kidney failure, pulmonary embolism (clot in a blood vessel supplying the lungs), gastrointestinal perforation (holes in the wall of the gut), and internal haemorrhages (bleeding).

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

Why has Sutent been approved?

The CHMP decided that Sutent's benefits are greater than its risks and recommended that it be given marketing authorisation.

Sutent was originally given 'conditional approval' because there was more evidence to come about the medicine, in particular in the treatment of renal cell carcinoma. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

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

A risk management plan has been developed to ensure that Sutent 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 Sutent, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Sutent

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Sutent on 19 July 2006. This was switched to a full marketing authorisation on 11 January 2007.

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

This summary was last updated in 08-2014.