

**EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)****SUTENT****EPAR summary for the public**

*This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.*

*If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).*

**What is Sutent?**

Sutent is a medicine containing the active substance sunitinib. It is available as capsules (orange: 12.5 mg; caramel and orange: 25 mg; caramel: 50 mg).

**What is Sutent used for?**

Sutent is used to treat patients with one of 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 GIST patients with tumours that cannot be removed with surgery, or that have spread to other organs, when treatment with imatinib (another anticancer medicine) has failed or cannot be tolerated by the patient;
- renal cell carcinoma (RCC), a type of kidney cancer. Sutent is used when the cancer is at an advanced stage, or has spread to other organs.

The medicine can only be obtained with a prescription.

**How is Sutent used?**

Treatment with Sutent should only be initiated by doctors who have experience in the treatment of GIST or RCC. Sutent is given in six-week cycles, with 50 mg a day for four weeks, followed by two weeks off treatment. Although the recommended dose is 50 mg, this can be adjusted to a higher or lower dose according to the patient's response to the treatment, provided that the dose does not go below 25 mg or above 75 mg.

**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, such as the 'KIT' receptors on the surface of GIST cells and similar receptors on the surface of RCC cells, where they are involved in the growth and spread of cancer cells. By blocking these enzymes, Sutent can reduce the growth and spread of the cancer.

**How has Sutent been studied?**

The effects of Sutent were first tested in experimental models before being studied in humans. The effectiveness of Sutent in GIST was studied in 312 patients who could not receive imatinib, or for whom treatment with imatinib had failed. Sutent was compared with placebo (a dummy treatment).

The study was double blinded (neither the doctor nor the patient knew which treatment the patient was receiving), and it measured the time taken for the disease to get worse.

In RCC, Sutent was studied in 750 patients whose cancer had not been treated before. The study compared the effects of Sutent and interferon alfa (the standard first-line treatment for this type of cancer). The main measure of effectiveness was 'progression-free survival' (the length of time until the cancer got worse or the patient died).

#### **What benefit has Sutent shown during the studies?**

Sutent was more effective than placebo in GIST: it took 27.3 weeks for the disease to get worse in patients who received Sutent and 6.4 weeks in patients who received placebo. The interim results (results calculated before the study was finished) were sufficiently good for the study to be stopped early and for the patients who were receiving placebo to be switched to Sutent.

In RCC, progression-free survival was longer in the patients taking Sutent. It took 47.3 weeks for the disease to get worse or the patient to die in the Sutent group, compared with 22.0 weeks in the group taking interferon alfa.

#### **What is the risk associated with Sutent?**

In clinical studies, the most common side effects with Sutent (seen in more than 1 patient in 10) were anaemia (low red blood cell counts), neutropenia (low white blood cell counts), thrombocytopenia (low blood platelet counts), hypothyroidism (underactive thyroid gland), decreased appetite, taste disturbance, headache, hypertension (high blood pressure), epistaxis (nosebleeds), diarrhoea, nausea (feeling sick), vomiting, stomatitis (inflammation of the lining of the mouth), dyspepsia (heartburn), abdominal (tummy) pain or distension (bloating), constipation, glossodynia (burning or tingling sensation around the mouth), flatulence (gas), oral (mouth) pain, dry mouth, yellow skin or skin discoloration, palmar-plantar erythrodysesthesia syndrome (swelling and numbness of the palms and soles of the feet), hair colour changes, rash, dry skin, alopecia (hair loss), pain in the extremities (hands and feet) or limbs, fatigue or asthenia (tiredness or weakness), mucosal inflammation (inflammation of the moist body surfaces), oedema (swelling) decreased ejection fraction (reduced amount of blood pumped out in each heartbeat) and decreased weight. For the full list of all side effects reported with Sutent, see the Package Leaflet.

Sutent should not be used in people who may be hypersensitive (allergic) to sunitinib or any of the other ingredients. Caution should be taken when it is given with some medicines, such as rifampicin (used in tuberculosis) or ketoconazole (an antifungal medicine). See the Package Leaflet for the list of the medicines that may interact with Sutent.

#### **Why has Sutent been approved?**

The Committee for Medicinal Products for Human Use (CHMP) decided that Sutent's benefits are greater than its risks for the treatment of unresectable and/or metastatic malignant GIST after failure of imatinib mesilate treatment due to resistance or intolerance, and for the treatment of advanced and/or metastatic RCC. The Committee recommended that Sutent be given marketing authorisation.

Sutent was originally given 'Conditional Approval'. This means that there was more evidence to come about the medicine, in particular in the treatment of renal cell carcinoma. As the company had supplied the additional information necessary, the authorisation was switched from 'conditional' to 'normal' approval on 11 January 2007.

#### **Other information about Sutent:**

The European Commission granted a marketing authorisation valid throughout the European Union for Sutent to Pfizer Ltd on 19 July 2006.

The full EPAR for Sutent can be found [here](#).

**This summary was last updated in 07-2008.**