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Sunitinib Accord (sunitinib)

An overview of Sunitinib Accord and why it is authorised in the EU

What is Sunitinib Accord and what is it used for?

Sunitinib Accord is a medicine used to treat adults with the following cancers:

- 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. Sunitinib Accord 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. Sunitinib Accord is used if the disease is getting worse and the tumour cells are well-differentiated (similar to normal cells in the pancreas).

Sunitinib Accord contains the active substance sunitinib and is a 'generic medicine'. This means that Sunitinib Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Sutent. For more information on generic medicines, see the question-and-answer document here.

How is Sunitinib Accord used?

Sunitinib Accord can only be obtained with a prescription and treatment should be started by doctors who have experience in the use of cancer medicines.

Sunitinib Accord is available as capsules of various strengths to be taken by mouth.

For GIST and metastatic renal cell carcinoma, Sunitinib Accord 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, Sunitinib Accord is given at a dose of 37.5 mg once a day without a rest period. This dose may also be adjusted.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

For more information about using Sunitinib Accord, see the package leaflet or contact your doctor or pharmacist.

How does Sunitinib Accord work?

The active substance in Sunitinib Accord, sunitinib, is a protein kinase inhibitor. This means that it blocks some specific enzymes known as protein kinases. These enzymes can be found 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, Sunitinib Accord can reduce the growth and spread of the cancer and cut off the blood supply that keeps cancer cells growing.

How has Sunitinib Accord been studied?

Studies on the benefits and risks of the active substance, sunitinib, in the authorised uses have already been carried out with the reference medicine, Sutent, and do not need to be repeated for Sunitinib Accord.

As for every medicine, the company provided studies on the quality of Sunitinib Accord. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Sunitinib Accord?

Because Sunitinib Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Sunitinib Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sunitinib Accord has been shown to have comparable quality and to be bioequivalent to Sutent. Therefore, the Agency's view was that, as for Sutent, the benefits of Sunitinib Accord outweigh the identified risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Sunitinib Accord are continuously monitored. Side effects reported with Sunitinib Accord are carefully evaluated and any necessary action taken to protect patients.

Other information about Sunitinib Accord

Sunitinib Accord received a marketing authorisation valid throughout the EU on 11 February 2021.

Further information on Sunitinib Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/sunitinib-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 02-2021.