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Sorafenib Accord (*sorafenib*)

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

What is Sorafenib Accord and what is it used for?

Sorafenib Accord is a cancer medicine used to treat patients who have the following diseases:

- hepatocellular carcinoma (a type of liver cancer);
- advanced renal cell carcinoma (a type of kidney cancer) when cancer treatment with interferon alpha or interleukin-2 has failed or cannot be used;

Sorafenib Accord contains the active substance sorafenib.

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

How is Sorafenib Accord used?

Sorafenib Accord can only be obtained with a prescription. Treatment with Sorafenib Accord should be supervised by doctors who have experience in using cancer treatments.

Sorafenib Accord is given as two tablets twice a day, without food or with a meal that has a low or moderate fat content. Treatment should continue as long as the patient continues to benefit from it without too many side effects. To manage side effects, treatment may be temporarily interrupted or the dose may be reduced.

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

How does Sorafenib Accord work?

The active substance in Sorafenib Accord, sorafenib, is a protein kinase inhibitor. This means that it blocks some specific enzymes known as protein kinases that are involved in the growth and spread of cancer cells, as well as in the development of new blood vessels supplying the tumours. By blocking these enzymes, Sorafenib Accord can reduce the growth of cancer cells and cut off the blood supply that keeps them growing.

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How has Sorafenib Accord been studied?

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

As for every medicine, the company provided studies on the quality of Sorafenib Accord. The company also carried out a study 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 Sorafenib Accord?

Because Sorafenib 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 Sorafenib Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sorafenib Accord has been shown to have comparable quality and to be bioequivalent to Nexavar. Therefore, the Agency's view was that, as for Nexavar, the benefits of Sorafenib 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 Sorafenib Accord?

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

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

Other information about Sorafenib Accord

Sorafenib Accord received a marketing authorisation valid throughout the EU on 9 November 2022.

Further information on Sorafenib Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/sorafenib-accord.

This overview was last updated on 11-2022.