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EPAR summary for the public

Nexavar

sorafenib

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

What is Nexavar?

Nexavar is a cancer medicine that contains the active substance sorafenib. It is available as tablets (200 mg).

What is Nexavar used for?

Nexavar is 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 anticancer treatment with interferon alfa or interleukin 2 has failed or cannot be used;
- differentiated thyroid carcinoma (a type of cancer originating from the follicular cells of the thyroid gland) when the cancer has progressed or spread locally or to other parts of the body and does not respond to treatment with radioactive iodine.

Because the numbers of patients with these diseases are low, the diseases are considered ‘rare’, and Nexavar was designated an ‘orphan medicine’ (a medicine used in rare diseases).

The medicine can only be obtained with a prescription.

How is Nexavar used?

Treatment with Nexavar should be supervised by doctors who have experience of anticancer treatments.

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Nexavar is given as two tablets twice a day, without food or with a meal that is low in fat. The treatment is continued as long as the patient continues to benefit from it without too many side effects. To manage side effects, treatment may have to be temporarily interrupted or the dose may be reduced.

How does Nexavar work?

The active substance in Nexavar, sorafenib, 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 on 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, Nexavar can reduce the growth of cancer cells and cut off the blood supply that keeps cancer cells growing.

How has Nexavar been studied?

Nexavar has been compared with placebo (a dummy treatment) in three main studies. The first study involved 602 patients with hepatocellular carcinoma; the second involved 903 patients with advanced renal cell carcinoma in whom one previous anticancer treatment had stopped working; and the third study involved 417 patients with differentiated thyroid carcinoma that had progressed or spread locally or to other parts of the body and did not respond to treatment with radioactive iodine. The main measures of effectiveness were how long the patients survived or how long the patients lived without their disease getting worse.

What benefit has Nexavar shown during the studies?

Nexavar was more effective than placebo in increasing how long the patients survived or how long the patients lived without their disease getting worse.

In the study of hepatocellular carcinoma, the patients taking Nexavar survived for an average of 10.7 months, compared with 7.9 months in those taking placebo.

In the study of renal cell carcinoma, the patients taking Nexavar survived for an average of 19.3 months, compared with 15.9 months in those taking placebo. This finding was based on the results from all 903 patients, including about 200 who had switched from placebo to Nexavar before the end of the study. The patients taking Nexavar lived for longer without their disease getting worse (167 days, around five and a half months) than those who took placebo (84 days, around three months). This finding was based on the results from 769 patients.

In the study in differentiated thyroid carcinoma, the patients taking Nexavar lived for an average of 10.8 months without their disease getting worse, compared with 5.8 months in those taking placebo.

What is the risk associated with Nexavar?

The most common side effects with Nexavar are diarrhoea, rash, alopecia (hair loss), infection, hand foot skin reaction (rash and pain on the palms of the hands and soles of the feet) and fatigue (tiredness). The most important serious side effects are myocardial infarction (heart attack) or ischaemia (reduced oxygen supply to the heart), gastrointestinal perforation (a hole that develops in the wall of the gut), drug-induced hepatitis (a disease of the liver), haemorrhage (bleeding) and hypertension or hypertensive crisis (high blood pressure).

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

Why has Nexavar been approved?

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

Other information about Nexavar

The European Commission granted a marketing authorisation valid throughout the European Union for Nexavar on 19 July 2006.

The summaries of the opinions of the Committee for Orphan Medicinal Products for Nexavar can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designations:

- renal cell carcinoma (29 July 2004)
- hepatocellular carcinoma (11 April 2006)
- papillary thyroid cancer and follicular thyroid cancer (13 November 2013)

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

This summary was last updated in 05-2014.