

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NEXAVAR

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 Nexavar?

Nexavar is a medicine containing the active substance sorafenib. It is available as red, round tablets (200 mg).

What is Nexavar used for?

Nexavar is used to treat patients who have:

- hepatocellular carcinoma,
- advanced renal cell carcinoma (a type of kidney cancer that affects the cells of the renal tubules) when anticancer treatment with interferon alfa or interleukin-2 has failed or cannot be used.

Because the numbers of patients with hepatocellular carcinoma and renal cell carcinoma are low, the diseases are considered 'rare', and Nexavar was designated an 'orphan medicine' (a medicine used in rare diseases) on 11 April 2006 and 29 July 2004.

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. Nexavar is given as two tablets (400 mg) 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.

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. Nexavar works by slowing down the rate of growth of cancer cells and cutting off the blood supply that keeps cancer cells growing.

How has Nexavar been studied?

The effectiveness of Nexavar in hepatocellular carcinoma has been studied in one main study including 602 patients, and its effectiveness in advanced renal cell carcinoma has been studied in one main study including 903 patients in whom one previous anti-cancer treatment had stopped working. In both studies, Nexavar was compared with placebo (a dummy treatment) in a double-blind manner

(neither the doctor nor the patient knew which treatment the patient was receiving). The main measure of effectiveness in the hepatocellular carcinoma study was overall patient survival. The main measures of effectiveness in the advanced renal cell carcinoma study were overall patient survival and how long the patients survived without their disease getting worse.

What benefit has Nexavar shown during the studies?

Nexavar was more effective than placebo in lengthening the overall survival of the patients.

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 survived an average of 19.3 months on Nexavar compared with 15.9 months on placebo, based on data from 903 patients, including about 200 who had switched from placebo to Nexavar at the time of the analysis. Time until disease got worse was longer in patients treated with Nexavar (167 days, around five and a half months) than those who took placebo (84 days, around three months), based on data from 726 patients.

What is the risk associated with Nexavar?

In clinical studies, the most common side effects with Nexavar (seen in more than 1 patient in 10) were lymphopenia (low levels of lymphocytes, a type of white blood cell), hypophosphataemia (low levels of phosphate in the blood), haemorrhage (bleeding), hypertension (high blood pressure), diarrhoea, nausea (feeling sick), vomiting, rash, alopecia (hair loss), 'hand foot syndrome' (rash and pain on the palms and soles), erythema (redness), pruritus (itchiness), fatigue (tiredness), pain, and increased amylase and lipase (enzymes produced by the pancreas). For the full list of all side effects reported with Nexavar, see the Package Leaflet.

Nexavar should not be used in people who may be hypersensitive (allergic) to sorafenib or any of the other ingredients. Caution is needed when it is taken with other medicines. See the Package Leaflet for the list of the medicines that may interact with Nexavar.

Why has Nexavar been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that Nexavar's benefits are greater than its risks for the treatment of hepatocellular carcinoma, and of advanced renal cell carcinoma in patients who have failed prior interferon alfa or interleukin-2 based therapy, or who are considered unsuitable for such therapy. The Committee recommended that Nexavar be given marketing authorisation.

Other information about Nexavar:

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

The summaries of opinion of the Committee for Orphan Medicinal Products for Nexavar are available [here](#) (hepatocellular carcinoma) and [here](#) (renal cell carcinoma).

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

This summary was last updated in 11-2007.