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Voranigo (vorasidenib)

An overview of Voranigo and why it is authorised in the EU

What is Voranigo and what is it used for?

Voranigo is a cancer medicine used to treat cancers of the brain called astrocytoma or oligodendroglioma in adults and adolescents from 12 years of age who weigh at least 40 kg, have had surgery as their only treatment and do not need other treatments such as radiotherapy or chemotherapy immediately.

It is used for tumours that are mainly slow growing (grade 2) and when the cancer cells have specific changes in the genes (mutations) that make proteins known as isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2).

Voranigo contains the active substance vorasidenib.

How is Voranigo used?

The medicine can only be obtained with a prescription. Treatment should be started and supervised by a doctor experienced in the use of cancer medicines.

Before treatment starts, the doctor will carry out tests to check whether the cancer cells have mutations in genes for IDH1 and IDH2.

Voranigo is available as tablets which the patient should take once a day by mouth at about the same time each day. The patient should not eat at least 2 hours before and 1 hour after taking Voranigo. Treatment lasts for as long as the patient benefits from it and does not have intolerable side effects.

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

How does Voranigo work?

In patients with astrocytoma or oligodendroglioma who have mutations in the genes for the IDH1 and IDH2 protein, these proteins do not work properly, causing the production of high levels of a substance called 2-hydroxyglutarate (2-HG).

2-HG causes changes in the way cells grow and mature, leading to the development of tumours. The active substance in Voranigo, vorasidenib, blocks the activity of the abnormal IDH1 and IDH2 proteins,

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thereby reducing levels of 2-HG. This allows the cells to grow and mature normally, preventing the tumour from growing.

What benefits of Voranigo have been shown in studies?

A main study involved 331 patients with grade 2 oligodendroglioma or astrocytoma with an IDH1 or IDH2 mutation and who had undergone surgery at least once to remove the tumour. The results showed that Voranigo was effective at preventing the disease from getting worse. In this study patients who had Voranigo lived for around 28 months without the disease getting worse, while those who had a placebo (a dummy treatment) lived for around 11 months without their disease worsening.

What are the risks associated with Voranigo?

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

The most common side effects with Voranigo (which may affect more than 1 in 10 people) include raised levels of liver enzymes, tiredness and diarrhoea.

Some side effects can be serious. The most frequent (which may affect up to 1 in 10 people) include raised levels of liver enzymes.

Why is Voranigo authorised in the EU?

Voranigo is effective at slowing the worsening of low-grade astrocytoma or oligodendroglioma. The medicine can therefore help patients avoid aggressive treatments, such as chemotherapy or radiotherapy. The main side effects are related to liver problems, but most side effects in the main study were not considered serious. The known side effects are considered manageable and more information about the safety of the medicine will come from future studies.

The European Medicines Agency therefore decided that Voranigo's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

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

Other information about Voranigo

Voranigo received a marketing authorisation valid throughout the EU on 17 September 2025.

Further information on Voranigo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/voranigo

This overview was last updated in 09-2025.