swissmedic

Summary report on authorisation dated 9 May 2025

Voranigo® (active substance: vorasidenib)

Authorisation in Switzerland: 15 November 2024

Film-coated tablets for the treatment of adults with grade 2 astrocytoma or oligodendroglioma with an IDH1 or IDH2 mutation following surgery

About the medicinal product

Voranigo contains the active substance vorasidenib and is used to treat adult patients suffering from a grade 2 astrocytoma or oligodendroglioma. These tumours are characterised by mutations in the isocitrate dehydrogenase-1 and -2 (IDH1 and IDH2) genes. Astrocytomas and oligodendrogliomas are gliomas, i.e. tumours of the central nervous system. Grade 2 means that the tumours grow slowly and the disease situation can remain stable for a long time. Voranigo is used after surgical removal of the tumour and is intended for patients who do not subsequently require immediate chemotherapy or radiotherapy.

Since these gliomas are rare and potentially life-threatening diseases, Voranigo has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Voranigo was authorised as part of "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. In addition to the FDA, the US regulatory authority, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Canada (HC), Israel (MOH), Singapore (HSA), Switzerland (Swissmedic), and the United Kingdom (MHRA) are currently represented in Project Orbis.

Mode of action

Voranigo, containing the active substance vorasidenib, targets the genetically modified (mutated) enzymes IDH1 and IDH2, which are present in certain brain tumours, including astrocytomas and oligodendrogliomas. These mutations lead to the excessive production of a harmful substance called 2-hydroxyglutarate (2-HG), which promotes tumour formation. 2-HG interferes with cell growth and cell division, thereby contributing to the formation and growth of tumours in the brain.

Voranigo inhibits these mutated enzymes, thereby reducing the production of 2-HG

and helping to slow down, or even stop, tumour growth.

Use

Voranigo is a prescription-only medicine and is available as a film-coated tablet in 10 mg and 40 mg doses in packs of 30 film-coated tablets. The recommended dosage is 40 mg once daily for patients weighing at least 40 kg. The tablets should be swallowed whole and taken at about the same time each day. To ensure that the full dose is taken, they should not be crushed, chewed or split. Nothing should be eaten for at least 2 hours before, and up to 1 hour after, administration.

Before treatment is started, the presence of a mutation of the IDH1 or IDH2 enzyme must be confirmed by a recognised test.

Efficacy

The efficacy of Voranigo was investigated in 331 patients taking part in a study called INDIGO. The participants had a grade 2 astrocytoma or oligodendroglioma with an IDH1 or IDH2 mutation and were treated either with Voranigo or placebo. The study showed that Voranigo significantly prolongs progression-free survival[1] (PFS). The median[2] PFS was 27.7 months in the Voranigo group compared to 11.1 months in the placebo group. Voranigo also significantly improved the time to the next tumour treatment.

Precautions, undesirable effects, and risks

Voranigo must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most frequent undesirable effects include increased liver enzymes, tiredness (33%), diarrhoea (21%) abdominal pain (12%) and a decreased platelet count (11%). Checking the blood count and liver function before starting and during treatment is recommended.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

To date, no specific drug treatment option has been available for patients with grade 2 astrocytoma or oligodendroglioma who do not require immediate chemotherapy or radiotherapy after a surgical intervention. The INDIGO study showed that treatment with Voranigo significantly prolongs the progression-free period and the time to the next tumour treatment compared to placebo, which represents a positive influence of the

[1] **PFS:** Progression-free survival: Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[2] **Median**: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always less than the median, the other half are always greater.

medicinal product on the course of the disease. An increase in liver enzymes was a fairly common reaction, but this was manageable with appropriate monitoring and dose adjustment. Taking all the risks and precautions into account, and based on the available data, the benefits of Voranigo outweigh the risks. Swissmedic has therefore authorised the medicinal product Voranigo, containing the active substance vorasidenib, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Voranigo®

Information for patients (package leaflet): Information for patients Voranigo®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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