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# Bavencio (*avelumab*)

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

## What is Bavencio and what is it used for?

Bavencio is a cancer medicine used to treat adults with Merkel cell carcinoma (MCC), a type of skin cancer, when the cancer has spread to other parts of the body.

Bavencio is also used in combination with another cancer medicine, axitinib, for the initial treatment of patients with advanced renal cell carcinoma (RCC, a cancer of the kidney).

Bavencio contains the active substance avelumab.

## How is Bavencio used?

Bavencio can only be obtained with a prescription, and treatment should be started and monitored by a doctor experienced in the treatment of cancer.

Bavencio is given in a dose of 800 mg once every 2 weeks as an infusion (drip) into a vein that lasts around 1 hour. Treatment should continue as long as the patient benefits from it or side effects become unacceptable.

Before the first 4 infusions of Bavencio, the patient receives an antihistamine and paracetamol to help prevent infusion-related reactions, such as reddening of the skin, chills, fever, back or abdominal (belly) pain, allergic reactions and difficulty breathing. If no reactions have occurred by the fourth infusion, the treating doctor may decide to stop giving these medicines before subsequent infusions. Treatment may need to be delayed or stopped if certain side effects occur.

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

## How does Bavencio work?

The active substance in Bavencio, avelumab, is a monoclonal antibody, a type of protein designed to recognise and attach to a protein called 'programmed death-ligand-1' (PD-L1), which is present on the surface of many cancer cells. PD-L1 usually attaches to cells of the immune (defence) system called T cells, preventing the T cells from attacking the cancer cells. By attaching to PD-L1, Bavencio prevents

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the cancer cells from switching off the T cells, thereby increasing the ability of the T cells to kill the cancer cells.

## What benefits of Bavencio have been shown in studies?

Bavencio has been shown to be of benefit in one main study that showed the cancer shrank in patients with MCC and one that showed patients with RCC could live longer without their disease getting worse. Although the dose of Bavencio in these studies was based on the patients' body weight, the company also supplied supporting data to show that Bavencio could be given in a standard dose, regardless of weight.

**Merkel cell carcinoma**

In a main study, around 33% of patients with MCC who had received previous treatment (29 out of 88) had a reduction in tumour size or no sign of it after treatment with Bavencio; in most of these patients, the response lasted for at least 6 months.

Results from the same study for 116 patients with metastatic MCC who had not received chemotherapy in the previous 6 months showed an overall response rate of 40%.

**Renal cell carcinoma**

In a main study involving 886 patients with advanced RCC, who had not been previously treated, Bavencio infusion in combination with axitinib by mouth was compared with standard treatment using another cancer medicine, sunitinib. The average time patients lived without their disease getting worse was around 13 months in those given Bavencio and axitinib versus 8 months in those given sunitinib. Longer follow-up is needed to draw a reliable conclusion on how well patients given Bavencio and axitinib survive overall.

## What are the risks associated with Bavencio?

The most common side effects with Bavencio used alone (which may affect more than 1 in 10 people) include tiredness, nausea (feeling sick), diarrhoea, decreased appetite, constipation, infusion-related reactions, weight loss and vomiting. Serious side effects include immune-related and infusion-related reactions, anaemia (low red blood cell counts), difficulty breathing and abdominal pain.

When Bavencio is used with axitinib the most common side effects of the combination, which may affect more than 1 in 5 people, are diarrhoea, high blood pressure, tiredness, nausea, dysphonia (hoarseness), decreased appetite, hypothyroidism (reduced thyroid function), cough, headache, breathing difficulties and arthralgia (joint pain).

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

## Why is Bavencio authorised in the EU?

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

Patients with MCC that has spread and come back after initial treatment with chemotherapy have very limited treatment options. Although the response rates to Bavencio are not outstanding, the duration of the response (at least 6 months) is important for these patients, since the responses seen with chemotherapy medicines are of shorter duration. In addition, data from the study show that some

patients who have not had previous chemotherapy also respond to treatment with Bavencio, with a similar duration of response.

The safety of Bavencio for this use is consider.ed acceptable and side effects manageable with the additional measures put in place.

In patients with advanced RCC, Bavencio plus axitinib has been shown to improve the length of time patients survive without their disease getting worse, when compared with sunitinib, though how long patients survive overall remains to be shown. The side effects of the combination were consistent with what was expected, and were considered acceptable given the nature of the condition being treated.

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

The company that markets Bavencio will issue educational materials for patients containing important information about possible side effects of Bavencio, particularly immune-related reactions, and how to manage them.

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

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

## Other information about Bavencio

Bavencio received a conditional marketing authorisation valid throughout the European Union on 18 September 2017. This was switched to a full marketing authorisation on 19 August 2020.

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

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