

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

BAVENCIO®

avelumab (rch)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about BAVENCIO.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of treating you with BAVENCIO against the benefits expected for you.

If you have any concerns about receiving this medicine, talk to your doctor, nurse or the hospital pharmacist.

You should read this leaflet carefully and keep it in a safe place to refer to it later.

What BAVENCIO is used for

BAVENCIO contains the active substance avelumab, a monoclonal antibody, which is a protein designed to recognise and attach to a specific target in the body protein that helps the immune system to attack and destroy cancer cells.

BAVENCIO is used to treat a rare type of skin cancer called metastatic Merkel Cell Carcinoma (mMCC) whose disease has spread.

This medicine is available only with a doctor's prescription.

BAVENCIO will be given to you in hospital under the supervision of an experienced doctor.

Ask your doctor if you have any questions about why BAVENCIO has been prescribed for you.

Use in Children

The effectiveness of BAVENCIO in children under the age of 12 years has not been established.

Before starting treatment with BAVENCIO

You should not be given BAVENCIO

- if you are allergic (hypersensitive) to avelumab or any of the other ingredients of BAVENCIO. If you are not sure, talk to your doctor.

Before you are given BAVENCIO

Check with your doctor or nurse before you are given BAVENCIO if:

- you have an autoimmune disease (a condition where the body attacks its own cells) like Crohn's, ulcerative colitis or lupus
- you have a HIV, hepatitis B or hepatitis C infection
- you are taking any medicines that suppress your immune system

- you have had an organ transplant.

However, once you are treated with BAVENCIO, your doctor may give you corticosteroids to reduce any possible side effects that you may have during your treatment.

Talk to your doctor or nurse before receiving BAVENCIO as it may cause:

- problems with your lungs such as breathing difficulties, chest pain or cough. These may be signs of inflammation of the lungs (pneumonitis).
- problems with your liver (hepatitis). Signs and symptoms of hepatitis may include eye or skin yellowing (jaundice), pain on the right side of your stomach area, drowsiness, dark urine (tea colored), bleeding or bruising more easily than normal, tiredness.
- diarrhoea (watery, loose or soft stools) or more bowel movements than usual or any symptoms of inflammation of the intestines (colitis), such as blood in your stools or dark, tarry, sticky stools, severe stomach area (abdomen) pain or tenderness.
- problems with your hormone producing glands (including the thyroid, pituitary, and adrenal glands) that may affect how these glands work. Signs and symptoms that your glands are not working properly may include rapid heart beat, increased sweating, extreme tiredness, weight gain or weight

loss, feeling more hungry than usual, hair loss, changes in mood or behaviour, such as irritability or forgetfulness, feeling cold, constipation, your voice gets deeper, very low blood pressure, dizziness or fainting, nausea or vomiting, stomach area (abdomen) pain.

- Type 1 diabetes, including acid in the blood produced from diabetes (diabetic ketoacidosis).
- Problems with your kidneys.
- problems with your your muscles (myositis) such as muscle pain or weakness.
- problems with your your heart (myocarditis) such as trouble breathing, dizziness or fainting, fever, chest pain, chest tightness or flu like symptoms.
- infusion-related reactions, which may include chills, hives, shortness of breath, fever or back pain.

Tell your doctor immediately if you have any signs or symptoms of the possible side effects listed above or if your symptoms get worse.

Please note that these signs and symptoms are sometimes delayed, and may develop weeks or months after your last dose. Before treatment, your doctor will check your general health. You will also have blood tests during your treatment.

Do not try to treat your symptoms with other medicines.

Your doctor may:

- give you other medicines in order to prevent complications and reduce your symptoms
- withhold the next dose of BAVENCIO
- or stop your treatment with BAVENCIO altogether.

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant.

BAVENCIO must not be used during pregnancy as it may cause harm to your unborn baby.

Make sure you maintain adequate contraception during treatment and for at least one month after your last dose.

Breast-feeding

Tell your doctor if you are breastfeeding or wish to breastfeed.

It is unknown if BAVENCIO is passed into your breast milk. A risk to the breast-fed infant cannot be excluded.

You should not breastfeed during treatment and for at least one month after your last dose.

Using other medicines

Tell your doctor if:

- you are taking or have recently taken any other medicines, including medicines obtained without a prescription from your pharmacy, supermarket or health food shop.
- take other medicines that make your immune system weak, such as steroids.

Your doctor has more information on medicines to be careful with or to avoid while using BAVENCIO.

Ask your doctor for advice before taking any medicine during your treatment with BAVENCIO.

Do not take BAVENCIO after the expiry date printed on the pack.

- The expiry date refers to the last day of that month. If you take it after the expiry date has passed, it may not work well. Your pharmacist or nurse will check the expiry date on the packaging.

Do not take BAVENCIO if the product shows signs of deterioration.

- Your pharmacist or nurse will check the packaging for any signs of deterioration.

How to use BAVENCIO

A doctor experienced in the use of medicines for cancer will supervise your treatment with BAVENCIO. Trained nurses will administer BAVENCIO to you.

You will receive BAVENCIO as an infusion (a drip) into a vein (intravenously) over a period of 60 minutes, once every 2 weeks.

Your doctor will decide how many treatments you need.

You will also receive premedication (paracetamol and an antihistamine) prior to the first four infusions of BAVENCIO, and prior to further infusions of BAVENCIO if your doctors believes this is necessary. These premedications are given to help minimise potential reactions to the BAVENCIO infusion.

How much to use

BAVENCIO is a concentrated solution for infusion. Your doctor will calculate the correct dose and dilution for you based on your body weight. The recommended dose is 10 mg of BAVENCIO per kg of your body weight.

Depending on your dose, some or all of the content of the BAVENCIO vial has to be diluted with 0.9% or 0.45% saline solution before use. More than one vial may be necessary to obtain the required dose.

How long to use BAVENCIO for

Your doctor will decide how long you will receive BAVENCIO based on your response to the medicine and the type of cancer you have.

If you miss a dose

It is very important for you to keep all your appointments to receive BAVENCIO.

If you miss a dose, talk to your doctor or nurse and arrange another visit as soon as possible.

If you take too much

Immediately contact your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much BAVENCIO.

While you are being treated with BAVENCIO

Things you must do

Keep all appointments with your doctor and always discuss anything that worries you during or after treatment with BAVENCIO.

Before starting any new medicine, remind your doctor or pharmacist that you are receiving BAVENCIO.

Tell all the doctors, dentists and pharmacists who are treating you that you are receiving BAVENCIO.

If you become pregnant while you are treated with BAVENCIO, tell your doctor immediately.

Things you must not do

Do not stop going to your visits for treatment with BAVENCIO without checking with your doctor.

Your condition may worsen if you stop receiving BAVENCIO.

Things to be careful of

Be careful driving or operating machinery until you know how BAVENCIO affects you.

Treatment-related symptoms can affect your concentration and ability to react.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are having BAVENCIO.

All medicines, including BAVENCIO, can have unwanted side effects. Sometimes they are serious, most of the time they are not.

Be aware of important symptoms of inflammation. BAVENCIO acts on your immune system and may cause inflammation in parts of your body.

Inflammation may cause serious damage to your body and some inflammatory conditions may be life-threatening and need treatment or withdrawal of BAVENCIO.

Do not try to treat your symptoms with other medicines.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor to answer any questions you may have.

The following side effects have been reported in clinical trials with BAVENCIO.

Very common (may affect more than 1 in 10 people)

- feeling tired or weak
- muscle or back pain, stomach area pain, joint pain
- loose stools, vomiting, nausea, constipation
- swelling in the arms, feet or legs
- feeling less hungry, weight loss
- cough
- rash
- infusion-related reactions (see below)
- decrease in the number of red blood cells
- high blood pressure.

Infusion-related side effects

Tell your doctor or nurse if you experience any of the following symptoms, during or after treatment with BAVENCIO:

- fever
- chills
- shortness of breath
- dizziness.

Sometimes these symptoms may occur up to several hours later. To recognise early signs of these side effects, you will be monitored closely while you are receiving each infusion

Your doctor may consider reducing the infusion rate, stop the infusion temporarily or permanently in order to manage these symptoms.

Other side effects

Other side effects have also been reported in clinical trials with BAVENCIO. Tell your doctor, pharmacist or nurse if you notice any of the following:

- signs of problems with your liver: eye or skin yellowing, severe nausea or vomiting, pain on the right side of your stomach area, drowsiness, dark urine, bleeding or bruising more easily than normal, feeling less hungry than usual, tiredness or abnormal liver function tests
- signs of problems with your thyroid or adrenal glands: extreme tiredness, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, changes in mood or behaviour, such as irritability or forgetfulness, feeling cold, very low blood pressure, headache
- signs of problem with your intestines: diarrhoea, more bowel movements than usual, black stools, tarry, sticky stools or stools with blood or mucus, severe stomach pain or tenderness
- signs of problems with your lungs: shortness of breath, chest pain, coughing
- signs of type 1 diabetes may include feeling more hungry or thirsty than usual, needing to

- urinate more often, weight loss, and feeling tired
- signs of inflammation of the kidney may include abnormal kidney function tests urinating less than usual, blood in your urine, or swelling in your ankles
 - signs of problems with your heart: trouble breathing, dizziness or fainting, fever, chest pain, chest tightness or flu like symptoms
 - signs of problems with your muscles: muscle pain or weakness

If you experience them any time during or after receiving BAVENCIO, contact your doctor or nurse.

Tell your doctor immediately if you experience sudden or worsened breathing difficulties, especially if you also experience cough or fever.

Your doctor may ask you to do blood tests or other laboratory tests to monitor if you have developed side effects during your treatment with BAVENCIO.

Your doctor may also prescribe other medicines to help manage the side effects.

Limit your exposure to sunlight by wearing hat, protective clothing and sunscreen when you go outside.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you experience any other side effects not listed in this leaflet.

After being treated with BAVENCIO

Storage

Undiluted BAVENCIO must be kept in a refrigerator at 2° to 8°C, but it must not be frozen. Store in the original package in order to protect from light.

Each vial is intended for single use only. When the needed amount of solution has been withdrawn from the vial, any remaining concentrated solution must be discarded.

Product description

What it looks like

BAVENCIO is a clear, colourless, to slightly yellow solution. It is supplied in 10 mL colourless glass vials with a rubber stopper and aluminium seal. Each pack contains 1 vial.

Ingredients

The active ingredient in BAVENCIO is avelumab. Each 10 mL vial contains 200 mg avelumab.

The solution also contains the following inactive ingredients:

- mannitol
- glacial acetic acid
- polysorbate 20
- sodium hydroxide
- water for injections.

BAVENCIO solution does not contain any preservative.

Sponsor and Supplied by

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