BAVENCIO®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using BAVENCIO?

BAVENCIO contains the active ingredient, avelumab. BAVENCIO is used to treat certain types of cancer.

For more information, see Section 1. Why am I using BAVENCIO? in the full CMI.

2. What should I know before I use BAVENCIO?

Do not use if you have ever had an allergic reaction to BAVENCIO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use BAVENCIO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BAVENCIO and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use BAVENCIO?

- Prior to the first four infusions of BAVENCIO, you will be given paracetamol and an antihistamine. For subsequent infusions, these medicines will only be given if your doctor believe this is necessary.
- You will receive BAVENCIO as an infusion (a fluid drip) into a vein (intravenously) over a period of 60 minutes, once every 2 weeks.

More instructions can be found in Section 4. How do I use BAVENCIO? in the full CMI.

5. What should I know while using BAVENCIO?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using BAVENCIO.
Driving or using machines	• Treatment-related symptoms can affect your concentration and ability to react.

For more information, see Section 5. What should I know while using BAVENCIO? in the full CMI.

6. Are there any side effects?

Common side effects include feeling tired or weak; muscle, back, stomach area or joint pain; loose stools, vomiting, nausea, constipation; swelling in the arms, feet or legs; feeling less hungry, weight loss; cough; rash, itching, redness of the skin; fever, chills; shortness of breath; dizziness, headache; high blood pressure; low blood pressure; flushing; difficulty in speaking or breathing, hoarseness; urinary tract infection, burning sensation or frequent urge of urination.

Serious side effects include infusion-related reactions; inflammation of your lungs (pneumonitis), liver (hepatitis or liver toxicity when used in combination with axitinib), intestines (colitis) or diarrhoea, stomach (gastritis), hormone producing glands (thyroid, pituitary, and adrenal glands), pancreas (pancreatitis), kidneys, muscles (myositis, myasthenia gravis/myasthenic syndrome, polymyalgia rheumatica), bile ducts (sclerosing cholangitis), joints (arthritis), glands that make moisture for the body (Sjögren's syndrome), heart (myocarditis or major adverse cardiovascular events when used in combination with axitinib), eyes (uveitis), lungs, skin, eyes and/or lymph nodes (sarcoidosis), blood vessels (vasculitis); Type 1 diabetes, including a serious increased acid in the blood (diabetic ketoacidosis); an immune system disorder of nerve inflammation (Guillain-Barré Syndrome); low neutrophils (neutropenia). You may experience more than one side effect at the same time such as inflammation of your muscles (myositis), inflammation of the heart (myocarditis) and muscle weakness (myasthenia gravis).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

BAVENCIO®

Active ingredient: *avelumab (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BAVENCIO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BAVENCIO.**

Where to find information in this leaflet:

1. Why am I using BAVENCIO?
2. What should I know before I use BAVENCIO?
3. What if I am taking other medicines?
4. How do I use BAVENCIO?
5. What should I know while using BAVENCIO?
6. Are there any side effects?
7. Product details

1. Why am I using BAVENCIO?

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

BAVENCIO is used to treat a rare type of skin cancer called metastatic Merkel cell carcinoma (mMCC) where the disease has spread; a type of cancer in the bladder or urinary tract called urothelial carcinoma, when the disease is advanced or metastatic but has not progressed with platinum-based chemotherapy; or a type of kidney cancer called renal cell carcinoma (RCC), when it is advanced, in combination with another medicine, axitinib. It is important that you also read the Consumer Medicine Information for axitinib. If you have any questions about axitinib, ask your doctor.

2. What should I know before I use BAVENCIO?

Warnings

Do not use BAVENCIO if:

- you are allergic to avelumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions, including an autoimmune disease (a condition where the body attacks its own cells) like Crohn's, Guillain- Barré, ulcerative colitis or lupus. If you already have an autoimmune disease, your risk of immune-mediated side effects may be higher as BAVENCIO may cause inflammation in parts of your body. You may also experience frequent flares of your autoimmune disease, which in the majority of cases are mild;
- human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS); hepatitis B or hepatitis C; have had an organ transplant
- take any medicines for any other condition, including medicines that suppress your immune system

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

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

- problems due to inflammation of your lungs (pneumonitis)
- problems with your liver (hepatitis or liver toxicity when used in combination with axitinib)
- problems with your intestines (colitis) or diarrhoea
- problems with your stomach (gastritis)
- problems with your hormone producing glands (including the thyroid, pituitary, and adrenal glands)
- problems with your pancreas (pancreatitis)
- Type 1 diabetes, including a serious, sometimes life-threatening problem due to increased acid in the blood produced from diabetes (diabetic ketoacidosis).
- problems with your kidneys
- problems with your muscles (myositis, myasthenia gravis/myasthenic syndrome, polymyalgia rheumatica)
- problems with your bile ducts (sclerosing cholangitis)
- problems with your joints (arthritis)
- problems with your glands that make moisture for the body such as tears and saliva (Sjögren's syndrome)
- problems with your heart (myocarditis or major adverse cardiovascular events such as trouble breathing, chest discomfort, or swelling of lower legs or hands when used in combination with axitinib)
- problems with your eyes (uveitis)
- an immune system disorder that can cause nerve inflammation (Guillain-Barré Syndrome)
- low number of neutrophils (neutropenia)
- infusion-related reactions
- problems due to inflammation of your lungs, skin, eyes and/or lymph nodes (sarcoidosis)
- problems due to inflammation of the blood vessels (vasculitis)

You may experience more than one side effect at the same time, such as inflammation of your muscles (myositis), inflammation of the heart (myocarditis), and an illness that can cause muscle weakness (myasthenia gravis).

In addition, autoimmune haemolytic anaemia (headaches, short of breath, looking pale, and yellowing of the skin and/or eyes) and systemic inflammatory response syndrome (redness and swelling in the affected parts of your body, pain, loss of function of parts of your body, fatigue, fast heart rate, abnormal breathing, fever or low body temperature, shaking or chills, warm or clammy/sweaty skin, rash, confusion, agitation or other mental changes, loss of consciousness) have been reported with BAVENCIO or other products in this class (immune checkpoint inhibitors).

Should any of the above occur, your doctor may give you other medicines to prevent complications and reduce your symptoms; withhold the next dose of BAVENCIO; or stop your treatment with BAVENCIO altogether.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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.

Talk to your doctor if you are breastfeeding or intend 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.

Use in children

The effect of BAVENCIO in children, under the age of 12 years, with mMCC, has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with BAVENCIO and affect how it works.

These include medicines that affect your immune system, such as steroids.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BAVENCIO.

4. How do I use BAVENCIO?

Prior to the first four infusions of BAVENCIO, you will be given paracetamol and an antihistamine. For subsequent infusions, these medicines will only be given if your doctor believe this is necessary. These premedications are given to help minimise potential reactions to the BAVENCIO infusion.

How much to use

- A doctor experienced in the use of medicines for cancer will supervise your treatment with BAVENCIO.
- Depending on your cancer, the recommended dose is either 10 mg per kg of your body weight or 800 mg of BAVENCIO.
- BAVENCIO has to be diluted with 0.9% or 0.45% saline solution before use.
- Your doctor will calculate the correct dose and dilution for you.

When to use BAVENCIO

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

As BAVENCIO is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you think that you have used too much BAVENCIO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BAVENCIO?

Things you should do

Keep all appointments with your doctor so that your progress can be checked. Your doctor may do blood tests or other laboratory tests from time to time to prevent unwanted side effects during your treatment with BAVENCIO.

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

Call your doctor straight away if you:

- Become pregnant while you are being treated with BAVENCIO

Remind any doctor, nurse, dentist or pharmacist you visit that you are using BAVENCIO.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BAVENCIO affects you.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

BAVENCIO can cause serious side effects. 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 can lead to death. You may need treatment or withdrawal of BAVENCIO. These side effects may happen anytime during treatment or even after your treatment has ended.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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, itching, redness of the skin • fever, chills • shortness of breath • dizziness, headache • high blood pressure • low blood pressure • flushing • difficulty in speaking or breathing, hoarseness • urinary tract infection (UTI) such as burning sensation when urinating, or increased urge to urinate	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Signs of problems with your liver: • yellowing of the whites of the eyes or skin (jaundice), severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea coloured), bleeding or bruising more easily than normal, feeling less hungry than usual, tiredness or abnormal liver function tests	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** **Please note that these signs and symptoms are sometimes delayed, and may develop weeks or months after your last dose.**
Signs of problems with your thyroid, adrenal or pituitary glands (hormone producing glands): • extreme tiredness, rapid heartbeat, increased sweating, weight changes, changes in mood or behaviour, such as irritability or forgetfulness, feeling cold, very low blood pressure (fainting, dizziness, fatigue, nausea), headache **Signs of problems with your intestines:** • diarrhoea (loose stools), more bowel movements than usual, blood in your stools or dark, tarry, sticky stools, severe stomach area (abdomen) pain or tenderness **Signs of problems with your stomach:** • stomach (abdomen) pain or tenderness, nausea, vomiting **Signs of problems with your lungs:** • breathing difficulties, coughing **Signs of problems with your endocrine pancreas gland (Type 1 diabetes including a serious, sometimes life-threatening problem due to increase acid in the blood produced from diabetes (diabetic ketoacidosis)):** • feeling more hungry or thirsty than usual, needing to urinate more often, weight loss, and feeling tired, having difficulty thinking clearly, breath that smells sweet or fruity, feeling sick or being sick, stomach pain, deep or fast breathing **Signs of problems with your kidneys:** • abnormal kidney function tests, needing to urinate 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, swelling in lower legs or hands, or flu-like symptoms **Signs of problems with your muscles:**	

Serious side effects	What to do
• muscle pain, stiffness, or weakness **Signs of problems with your pancreas:** • abdominal pain, nausea, vomiting **Signs of problems with your eyes:** • eye pain, eye redness, sensitivity to light, blurred or cloudy vision, small shapes moving across your field of vision (floaters), loss of peripheral vision (the ability to see objects at the side of your field of vision) **Signs of problems with your bile ducts:** • pain in the upper right part of the stomach • swelling of the liver or spleen • fatigue • itching • yellowing of the skin or the whites of the eyes **Signs of problems with your joints:** • joint pain, stiffness or swelling **Signs of problems with your glands that make moisture for the body:** • dry eyes • dry mouth **Guillain-Barré Syndrome (an immune system disorder that can cause nerve inflammation):** • pain, numbness, muscle weakness, difficulty walking **Changes in laboratory test results:** • low number of neutrophils, a type of white blood cell that helps fight infections **Signs of problems in other organs:** • swollen lymph nodes, rash or tender lumps on skin, cough or eye pain (sarcoidosis) **Signs of problems with your blood vessels:** • fever, tiredness, weakness, muscle aches and pains, numbness, headache, weight loss, redness in eyes or skin, bleeding, bruising, lumps or swelling.	

Serious side effects	What to do
Signs of an allergic reaction (anaphylactic reaction and/or hypersensitivity): • shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin **Infusion-related:** • fever • back and/or abdominal pain • chills or shaking • shortness of breath or wheezing • bumpy rash or skin wheals (hives) • flushing • low blood pressure (dizziness, fatigue, nausea) 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 to manage these symptoms.	

Immune checkpoint inhibitor class effects

There have been cases of the following side effects reported during treatment with other products in this class which might also occur during treatment with BAVENCIO:

- lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency).
- coeliac disease (characterised by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods).
- aplastic anaemia (when the bone marrow fails to produce enough new blood cells).

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What BAVENCIO contains

Active ingredient (main ingredient)	avelumab (rch)
Other ingredients (inactive ingredients)	Mannitol, glacial acetic acid, polysorbate 20, sodium hydroxide, water for injections
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What BAVENCIO looks like

BAVENCIO is a clear, colourless, to slightly yellow solution. It is supplied in 20 mL colourless glass vials with a rubber stopper and aluminium seal. Each pack contains 1 vial. (Aust R 282729).

Who distributes BAVENCIO

Merck Healthcare Pty Ltd

Suite 1, Level 1

Building B

11 Talavera Road

Macquarie Park NSW 2113

Medical Information: 1800 633 463

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