



BAVENCIO®
(avelumab)

PATIENT ALERT CARD

IMPORTANT - This card contains important safety information of your avelumab treatment. Keep this card with you during your treatment and for another 3 months after your last treatment with avelumab. Always show it to any healthcare professional involved in your treatment.

This educational material is part of the conditions of the marketing authorization and has been approved by the Malta Medicines Authority on 12/09/2024
Date of preparation September 2024 – Version 7.0

Avelumab

Avelumab

Important safety information to minimize the risk of immune-mediated side effects.

The doctor has prescribed Bavencio® (avelumab) to treat your cancer and like all medicines, it can cause side effects, although not everybody gets them. Bavencio® acts on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and in rare cases some inflammatory conditions may lead to death. Your risk of these side effects may be higher if you already have an autoimmune disease (a condition where the body attacks its own cells). You may also experience frequent flares of your autoimmune disease, which in the majority of cases, are mild. These side effects may happen at any time during treatment or even after your treatment has ended.

For further information, consult the Bavencio® Package information Leaflet or call Vivian Corporation Ltd on +35622588600.

Contact your doctor right away if you develop any of the signs or symptoms described in this card or if they get worse. Your doctor may give you other medicines to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of Bavencio® or completely stop treatment if your side effects are too severe.

Infusion-related reactions:

- Shortness of breath or wheezing
- Chills or shaking
- Bumpy rash or skin wheals
- Flushing
- Low blood pressure (dizziness, fatigue, nausea)
- Fever
- Back pain
- Abdominal pain

Lung problems (inflammation of the lungs):

- Breathing difficulties
- Cough

Liver problems (inflammation of the liver):

- Yellowing of skin and whites of your eyes (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 usual
- Feeling less hungry than usual
- Tiredness
- Abnormal liver function tests

Intestinal problems (inflammation of the intestines):

- Diarrhoea (loose stools)
- More bowel movements than usual
- Blood in your stools or dark, tarry, sticky stools
- Severe stomach (abdomen) pain or tenderness

Pancreas problems (inflammation of the pancreas):

- Abdominal pain
- Nausea
- Vomiting

Heart problems (inflammation of the heart):

- Trouble breathing
- Dizziness or fainting
- Fever
- Chest pain and chest tightness
- Flu-like symptoms

Hormone glands problems (inflammation of the hormone producing glands especially thyroid, pituitary, adrenal):

- Extreme tiredness
- Rapid heartbeat
- Increased sweating
- Changes in mood or behavior, such as irritability or forgetfulness
- Feeling cold
- Very low blood pressure (fainting, dizziness, fatigue, nausea)
- Weight change
- Headache

Endocrine pancreas gland (Type 1 diabetes including a serious, sometimes life-threatening problem due to increased acid in the blood produced from diabetes (diabetic ketoacidosis)):

- Feeling more hungry or thirsty than usual
- Need to urinate more often
- Weight loss
- Feeling tired
- Having difficulty thinking clearly
- Breath that smells sweet or fruity
- Feeling sick or being sick
- Stomach pain
- Deep or fast breathing

Kidney problems (inflammation of the kidneys):

- Abnormal kidney function tests
- Urinating less than usual
- Blood in your urine
- Swelling in your ankles

Other organs:

Muscle problems (inflammation of muscle):

- Muscle pain or weakness

Eye problems (inflammation of the eye (uveitis)):

- 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)

Nervous system problems:

Guillain-Barre Syndrome:

- Pain
- Numbness
- Muscle weakness
- Difficulty walking

Myasthenia gravis, myasthenic syndrome:

- Muscle weakness

IMPORTANT

- Do not stop treatment with Bavencio® unless you have discussed this with your doctor as it may stop the effect of the medicine. Please try to keep all your appointments and reschedule as soon as possible if you miss one.
- Do not attempt to diagnose or treat side effects by yourself.
- **Carry this Alert Card with you at all times**, especially when you travel, whenever you go to the Accident and Emergency department, or when you must see another doctor, nurse or pharmacist. Carry this card for at least 3 months following the end of your treatment with Bavencio®.
- Be sure to notify any healthcare professional you see that you are being treated with Bavencio® and show them this card.

If you get any side effects, talk to your doctor, pharmacist or nurse right away. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly to the Malta Medicines Authority via the website www.medicinesauthority.gov.mt/adrportal or to Vivian Corporation Ltd via phone +35622588600 or e-mail pv@viviancorp.com. By reporting side effects, you can provide more information on the safety of this medicine.

IMPORTANT INFORMATION FOR HEALTH CARE PROVIDERS

This patient is being treated with Bavencio®, which can cause infusion-related reactions as well as immune-mediated adverse reactions that may appear any time during treatment or after treatment. Early diagnosis and appropriate management are essential to minimize any consequences of immune-mediated adverse reactions.

For suspected immune-mediated adverse reactions, adequate evaluation should be performed to confirm aetiology or exclude other causes. Based on the severity of the adverse reaction, Bavencio® should be withheld and corticosteroids administered. If corticosteroids are used to treat an adverse reaction, a taper of at least 1 month duration should be initiated upon improvement.

In patients whose immune-mediated adverse reactions cannot be controlled with corticosteroid use, administration of other systemic immunosuppressants may be considered. Specific guidelines for managing immune-mediated adverse reactions are available in the Product Information of Bavencio®. Please contact the patient's doctor who prescribed Bavencio® for more information.

Assess patients for signs and symptoms of immune-mediated adverse reactions (including immune-mediated pneumonitis, hepatitis, colitis, pancreatitis, myocarditis, endocrinopathies, thyroid disorders, adrenal insufficiency, type 1 diabetes mellitus, pituitary disorders), nephritis and renal dysfunction, and other immune-mediated adverse reactions [myositis, Guillain-Barré syndrome, uveitis, myasthenia gravis/ myasthenic syndrome] reported in patients receiving Bavencio®.

Please consult the Product Information of Bavencio® at <https://www.ema.europa.eu/en/medicines/human/EPAR/bavencio> or call Vivian Corporation Ltd on +35622588600 for more information.

IMPORTANT CONTACT INFORMATION

Name of Doctor who has prescribed Bavencio®

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)