

BAVENCIO®
(avelumab)

PATIENT CARD

IMPORTANT – This card contains important safety information that you need to be aware of before, during and after treatment with Bavencio®.

Keep this card with you in your wallet and show it to any healthcare professional involved in your treatment, not just your prescribing specialist doctor.

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Reporting Adverse Events
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.
In the Republic of Ireland, side effects can be reported to HPRA Pharmacovigilance at www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.
Adverse events can also be reported to Merck Serono Limited – Tel: 1 800 719 881 or by email to: medinfo.uk@merckgroup.com

BAVENCIO® (avelumab)

Important safety information to minimise the risk of immune-mediated side effects and infusion-related reactions

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. These side effects can be serious and may happen at any time during treatment or even after your treatment has ended.

Contact a specialist right away if you develop any of the signs or symptoms described in this card or if these symptoms persist or worsen. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of avelumab or completely stop treatment if your side effects are too severe.

For further information, consult the BAVENCIO® Patient Information Leaflet or call Merck Medical Information on 1800 719881.

Contact your specialist right away if you develop any signs or symptoms, which may include those listed below:

Infusion 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

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
- Needing 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

Nervous system problems

Guillain-Barre Syndrome:

- Pain
- Numbness
- Muscle weakness
- Difficulty walking

Myasthenia gravis, myasthenic syndrome:

- Muscle weakness

INFLAMMATORY REACTIONS:

Lung problems

- Breathing difficulties
- Cough

Liver problems

- Yellowing of skin or 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 normal
- Feeling less hungry than usual
- Tiredness
- Abnormal liver function tests

Intestinal problems

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

Stomach problems

- Stomach/abdomen pain or tenderness
- Nausea
- Vomiting

Pancreas problems

- Abdominal pain
- Nausea
- Vomiting

Heart problems

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

Hormone gland problems

- Extreme tiredness
- Rapid heart beat
- Increased sweating
- Changes in mood or behaviour, such as irritability or forgetfulness

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 yourself
- Carry this 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 HPRA Pharmacovigilance via www.hpra.ie.
- By reporting side effects you can help 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 and after treatment and involve a range of organ systems. Early diagnosis and appropriate management are essential to minimise 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 for 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 and myocarditis, [fatal cases reported for both conditions], endocrinopathies [thyroid disorder, adrenal insufficiency, type 1 diabetes mellitus [including diabetic ketoacidosis], pituitary disorders], nephritis) and renal dysfunction. Other immune-mediated adverse reactions reported in patients receiving BAVENCIO®, include, myositis, Guillain-Barre syndrome, uveitis, myasthenia gravis/ myasthenic syndrome, sclerosing cholangitis, arthritis, polymyalgia rheumatica, Sjogren's syndrome and gastritis.

Please consult the Summary
of Product Characteristics
for BAVENCIO® (avelumab) at
medicines.ie or call
Merck Medical Information on
Tel: 1800 719881
for more information.

IMPORTANT CONTACT INFORMATION

Name of Specialist

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)