

**BAVENCIO®** ▼  
(avelumab)

**PATIENT ALERT 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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IE-AVE-00003  
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▲ 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 via HPRa Pharmacovigilance, Website <http://www.hpra.ie>

**BAVENCIO®** ▲  
(avelumab)

Important safety information  
to minimise the risk of  
immune-related side effects

May cause serious side effects.

Contact a specialist right away if you develop any of the signs or symptoms listed below 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 stop treatment.

For further information, consult the 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-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

**Lungs**

- Breathing difficulties
- Cough

**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 normal
- Feeling less hungry than usual
- Tiredness
- Abnormal liver function tests

**Intestines**

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

**Hormone glands**

- Extreme tiredness
- Rapid heart beat

- Increased sweating
- Changes in mood or behaviour, 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
- 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

**Kidneys**

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

**Pancreas**

- Abdominal pain
- Nausea
- Vomiting

**Hear**

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

**Muscle**

- Muscle pain
- Weakness

**Eye**

- 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**

Guillain-Barre Syndrome:

- Pain
- Numbness
- Muscle weakness
- Difficulty walking

Myasthenia gravis, myasthenic syndrome:

- Muscle weakness

## IMPORTANT

- Do not attempt to diagnose or treat side effects 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
- Be sure to notify any healthcare professional you see that you are being treated with avelumab and show them this card
- 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. You can also report side effects directly via [www.hpra.ie](http://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® (avelumab), which can cause infusion-related reactions as well as immune-related adverse reactions that involve the lungs, liver, intestines, hormone producing glands (the thyroid, adrenal, pituitary and endocrine pancreas glands), kidneys and other organs. Early diagnosis and appropriate management are essential to minimise any consequences of immune-related adverse reactions.

For suspected immune related adverse reactions, adequate evaluation should be performed to confirm aetiology or exclude other causes. Based on the severity of the adverse event, avelumab 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-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants may be considered. Specific guidelines for managing

immune-related adverse reactions are available in the Summary of Product Characteristics for avelumab.

*Assess patients for signs and symptoms of pneumonitis, hepatitis, colitis, endocrinopathies including thyroid disorders (hypothyroidism/hyperthyroidism), adrenal insufficiency, type 1 diabetes mellitus including diabetic ketoacidosis, nephritis and renal dysfunction, and other immune-related adverse reactions reported in patients receiving avelumab: myocarditis including fatal cases, pancreatitis including fatal cases, myositis, hypopituitarism, uveitis, Guillain-Barré syndrome and myasthenia gravis, myasthenic syndrome.*

Please consult the Summary of Product Characteristics for BAVENCIO® (avelumab) at [medicines.ie](http://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)