

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 avelumab.

Keep this card with you during your treatment and for the following 3 months following the end of treatment with avelumab. Show it to any healthcare professional involved in your treatment, not just your prescribing specialist doctor.

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Avelumab

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

Contact a specialist right away if you develop any of the signs or symptoms described in this card.

For further information, consult the Patient Information Leaflet or call Merck Medical Information on +44 (0)208 818 7373.

Please keep this card with you, during your treatment and for 3 months following the end of your treatment with avelumab.

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

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

Bowel and stomach

- 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

Type 1 diabetes

- Feeling more hungry or thirsty than usual
- Needing to urinate more often
- Weight loss
- Feeling tired

Kidneys

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

Heart

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

Pancreas

- Abdominal pain
- Nausea
- Vomiting

Muscle

- Muscle pain or 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)

Immune system (Guillain-Barre Syndrome)

- Pain
- Numbness
- Muscle weakness
- Difficulty walking

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

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.
- 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 avelumab, which can cause infusion-related reactions as well as immune-related adverse reactions that involve the lungs, liver, intestines, hormone 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.

Please refer to the summary of product characteristics and the HCP FAQ document available at www.medicines.org.uk

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, 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, and Guillain-Barré syndrome.*

Please consult the Summary of Product Characteristics for avelumab at medicines.org.uk or call Merck Medical Information on Tel: +44 (0)208 818 7373 for more information.

IMPORTANT CONTACT INFORMATION

Name of Specialist

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)