

This PATIENT ALERT CARD format and content have been approved by the Ministry of Health during June 2022.

BAVENCIO[®]
(avelumab)

MERCK

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(avelumab)

**PATIENT
ALERT CARD**

Contact your specialist right away if you develop any of the signs or symptoms 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

Pneumonitis

- Breathing difficulties
- Cough

Hepatitis

- Yellowing of your skin (jaundice) and whites of your eyes
- 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

Colitis

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

Pancreatitis

- Abdominal pain
- Nausea
- Vomiting

Myocarditis

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

Hormone glands endocrinopathies

- 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 endocrinopathies (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
- Urinating 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

Nephritis and renal dysfunction

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

Other immune-related adverse reactions

Myositis

- Muscle pain
- Weakness

Uveitis (Inflammation of the eye)

Guillain-Barre Syndrome

- Pain
- Muscle weakness
- Numbness
- Difficulty in 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 Emergency department, or when you must see another doctor or other nurse or pharmacist
- 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. This includes any possible side effects not listed in the Patient's brochure

Important Information for Health Care Professionals

This patient is being treated with BAVENCIO®, which can cause infusion-related reactions as well as immune-related adverse reactions that can involve the lungs, liver, intestines, pancreas, heart, hormone producing glands (the thyroid, adrenal pituitary and endocrine pancreas glands), kidneys and other organs. Early diagnosis and appropriate management are essential to minimize 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 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-related adverse reactions cannot 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 Prescribing Information (PI) for BAVENCIO®.

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

Please consult the PI for BAVENCIO® (avelumab) at the Ministry of Health website or call Merck Medical department on Tel: 09-9510737 for more information.

Important Contact Information

Name of Doctor

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)



PATIENT ALERT CARD

BAVENCIO®

(avelumab)

Important safety information to minimize the risk of immune-related adverse reactions

May cause serious side effects. Contact your specialist right away if you develop any of the signs or symptoms listed below. 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 stop treatment.

For further information, please consult your doctor.

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 to Merck on Tel: 09-9510737 or by using the following email: Drug.Safety.israel@merckgroup.com

Side effects can be reported to the Ministry of Health by clicking on the "Report Side Effects of Drug Treatment" found on the ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects or by entering the link: <https://sideeffects.health.gov.il>