



Patient Information Brochure

BAVENCIO[®]

(avelumab)

**Important safety information
to minimise the risk of
immune-related side effects
(adverse reactions)**

Information for Patients

This patient information brochure was approved by the Ministry of Health during June 2022.

Introduction

Your doctor has prescribed you BAVENCIO® (avelumab) to treat your disease. This brochure will serve as a guide to your treatment, including what to expect while you are taking this medicine. This guide will explain some of the side effects that might occur while you undergo treatment with BAVENCIO® and how to recognize them. You will also learn why it is important to report any symptoms to your doctor right away.

Glue
Alert Card
Here

Doctor Stamp

About BAVENCIO® (avelumab)

BAVENCIO® is a medicine used to treat some types of cancer.

Before you start BAVENCIO®

Tell your doctor about any medications you are taking, have recently taken, or might take. Make sure your doctor knows if you:

- Have an autoimmune disease (a condition where the body attacks its own cells)
- Have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)
- Have ever had chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV)
- Receive medicines to suppress your immune system
- Have had an organ transplant
- Are taking or have recently taken any other medicines
- Are pregnant, think you may be pregnant, or are planning to have a baby
- Could become pregnant. You must use effective contraceptives while you are being treated with BAVENCIO® and for at least 1 month after your last dose
- Are breast-feeding or plan to breast-feed. Do not breast feed while receiving BAVENCIO® and for at least 1 month after your last dose

What you should know about your treatment

How you receive BAVENCIO® (avelumab)

BAVENCIO® will be given to you in a hospital or clinic under the supervision of an experienced doctor. Your doctor will give you BAVENCIO® through an infusion (a drip) into a vein (intravenously) over a period of 1 hour, every 2 weeks. Your doctor will decide how many treatments you need.

Before you receive BAVENCIO®

For at least the first 4 treatments, you will receive paracetamol and an antihistamine before being given BAVENCIO® to help prevent possible side effects related to the infusion. Depending on how your body responds to the treatment, your doctor may decide to continue giving you these medicines prior to all your BAVENCIO® treatments.

It is very important for you to keep all your appointments to receive BAVENCIO®. If you miss an appointment, ask your doctor to schedule your next dose.

BAVENCIO® can cause serious side effects that need to be treated straight away

Possible side effects

Like all medicines, BAVENCIO® can cause side effects, although not everyone 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 some inflammatory conditions may need additional treatment and your BAVENCIO® treatment may be withdrawn. In rare cases, some of these side effects may lead to death.

Seek urgent medical attention if you have any of these symptoms, or if they get worse. They may happen weeks or months after your last dose. Do not try to treat them on your own with other medicines:

Side Effects	Sign or Symptoms
Infusion reactions	<ul style="list-style-type: none"> • 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

Immune-related events	
Pneumonitis (inflammation of the lungs)	<ul style="list-style-type: none"> • Breathing difficulties • Cough
Hepatitis (inflammation of the liver)	<ul style="list-style-type: none"> • Yellowing of 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 test
Colitis (inflammation of the intestines)	<ul style="list-style-type: none"> • Diarrhea (loose stools) • More bowel movements than usual • Blood in your stools or dark, tarry, sticky stools • Severe stomach (abdomen) pain or tenderness
Pancreatitis (inflammation of the pancreas)	<ul style="list-style-type: none"> • Abdominal pain • Nausea • Vomiting
Myocarditis (inflammation of the heart)	<ul style="list-style-type: none"> • Trouble breathing • Dizziness or fainting • Fever • Chest pain and chest tightness • Flu-like symptoms
Hormone gland endocrinopathies (thyroid, pituitary, adrenal)	<ul style="list-style-type: none"> • 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, including a serious, sometimes life-threatening problem due to increased acid in the blood produced from diabetes (diabetic ketoacidosis)	<ul style="list-style-type: none"> • 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 (inflammation of the kidney) and renal dysfunction	<ul style="list-style-type: none"> • Abnormal kidney function tests • Urinating less than usual • Blood in your urine • Swelling in your ankles
Other immune-related adverse reactions	<p>Myositis (inflammation of muscle)</p> <ul style="list-style-type: none"> • Muscle pain • Weakness <p>Uveitis (Inflammation of the eye)</p> <p>Guillain-Barre Syndrome</p> <ul style="list-style-type: none"> • Pain • Numbness • Muscle weakness • Difficulty in walking <p>Myasthenia gravis, myasthenic syndrome:</p> <ul style="list-style-type: none"> • Muscle weakness

Watching for side effects

It is important to be aware of symptoms

If you notice any signs or symptoms while receiving BAVENCIO[®], you should talk to your doctor right away. Be aware that side effects may still occur weeks or months after receiving the last dose of BAVENCIO[®].

Certain medications, such as corticosteroids, may be used to prevent more severe complications and reduce your symptoms. Your doctor may delay or completely stop your treatment if your side effects are too severe.

What to do if symptoms occur when you are away from home

It is important that you contact your doctor whenever symptoms occur. Always carry your Alert Card with your doctor's contact information so that he or she may be reached in case of emergency. The Alert Card contains important information about symptoms that need to be reported immediately to the doctor or nurse treating you while you are away from home. It also alerts other doctors that you are being treated with BAVENCIO[®].

Carry your Alert Card with you at all times.

Don't miss an appointment for treatment with BAVENCIO[®]

If you stop or interrupt your treatment, it may stop the effect of the medicine. Do not stop treatment with BAVENCIO[®] unless you have discussed this with your doctor.

Please try your best to keep all your appointments and reschedule as soon as possible if you miss one. Contact your doctor immediately if you experience any side effects, including those not listed in this brochure.

BAVENCIO[®] is a type of therapy that works by helping your body's immune system fight your cancer. This type of therapy can sometimes have side effects.

With BAVENCIO[®], certain side effects can occur that may be severe. Contact your doctor right away if you experience any side effects. Speak with your doctor if you have any questions about BAVENCIO[®] or how it works.

Where to find further information

For more information, please consult your doctor.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this brochure.



Reporting side effects

This medicine is subject to additional monitoring. By reporting side effects, you can help provide more information on the safety of this medicine. This will allow quick identification of new safety information.

Please report side effects 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>