

Your Guide to Information for Patients

BAVENCIO[®] ▼
(avelumab)

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

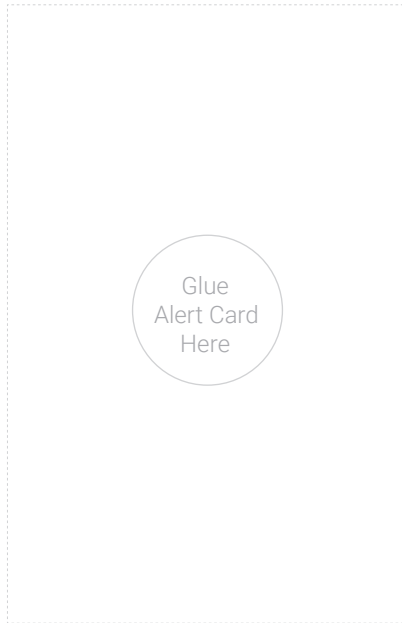
Information for Patients



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. Side effects may be reported via HPRA Pharmacovigilance, Website www.hpra.ie.

Introduction

Your doctor has prescribed avelumab to treat your cancer. Please refer to the Patient Information Leaflet to read what avelumab is and what it is used for. 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 avelumab and how to check for them. You will also learn why it is important to report any symptoms to your doctor right away.



Hospital Contact Details

About BAVENCIO® (avelumab)

Avelumab is a medicine used to treat some types of advanced cancer.

Before you start avelumab

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

- Are taking any other medicines including those you have recently taken or might take in the future
- 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
- Are a woman who could become pregnant. You must use effective contraceptives while you are being treated with avelumab and for at least 1 month after your last dose
- Are breast-feeding or plan to breast-feed. Do not breast feed while receiving avelumab and for at least 1 month after your last dose

What you should know about your treatment

How you receive BAVENCIO® (avelumab)

Avelumab will be given to you in a hospital or clinic under the supervision of an experienced doctor. You will be given avelumab 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 avelumab

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

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

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

Possible side effects

Like all medicines, avelumab can cause side effects, although not everyone gets them.

Avelumab 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 avelumab 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, or other, symptoms, or if they get worse. They may happen weeks or months after your last dose.

Do not try to treat yourself with other medicines:

Side Effects	Sign or Symptoms
Infusion-related 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
Lung problems (inflammation of the lungs)	<ul style="list-style-type: none"> • Breathing difficulties • Cough

Side Effects	Sign or Symptoms
Liver problems (inflammation of the liver)	<ul style="list-style-type: none"> • 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 (inflammation of the intestines)	<ul style="list-style-type: none"> • Diarrhoea (loose stools) • More bowel movements than usual • Blood in your stools or dark, tarry, sticky stools • Severe stomach (abdomen) pain or tenderness
Hormone gland problems (inflammation of the hormone producing glands especially thyroid, pituitary, adrenal)	<ul style="list-style-type: none"> • Extreme tiredness • Rapid heartbeat • 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 • 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

Side Effects	Sign or Symptoms
Kidney problems (inflammation of the kidney)	<ul style="list-style-type: none"> • Abnormal kidney function tests • Urinating less than usual • Blood in your urine • Swelling in your ankles
Pancreas problems (Inflammation of the pancreas)	<ul style="list-style-type: none"> • Abdominal pain • Nausea • Vomiting
Heart problems (inflammation of the heart)	<ul style="list-style-type: none"> • Trouble breathing • Dizziness or fainting • Fever • Chest pain and chest tightness • Flu-like symptoms
Muscle problems (inflammation of muscle)	<ul style="list-style-type: none"> • Muscle pain • Weakness
Eye problems (inflammation of the eye)	<ul style="list-style-type: none"> • 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 problems	<p>Guillain-Barre Syndrome:</p> <ul style="list-style-type: none"> • Pain • Numbness • Muscle weakness • Difficulty 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 avelumab, 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 avelumab.

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 or nurse 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 a doctor or nurse treating you while you are away from home. It also alerts other doctors that you are being treated with avelumab.

Carry your Alert Card with you at all times.

Don't miss an appointment for treatment with BAVENCIO® (avelumab)

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

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

Please contact your doctor if you have any questions about avelumab or how it works.

Don't forget

BAVENCIO® (avelumab) 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 avelumab, 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 avelumab or how it works.

Where to find further information

For more information, consult the BAVENCIO Patient Information Leaflet (PIL) at www.medicines.ie or call Merck Medical Information on 1800 719881.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet.

Reporting side effects

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 HPRA Pharmacovigilance, Website <http://www.hpra.ie>

By reporting side effects, you can help provide more information on the safety of this medicine.