

Your Guide to Information for Patients


BAVENCIO[®]

(avelumab)

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

Information for Patients

Doctor Stamp



Introduction

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

About BAVENCIO[®] (avelumab)

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

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.

Before you start BAVENCIO

Tell your doctor about any medicines 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 avelumab and for at least 1 month after 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)

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.

Please refer to the product information for the recommended dose of BAVENCIO.

Before you receive BAVENCIO

For at least the first 4 treatments, you will receive paracetamol and an antihistamine before being given BAVENCIO 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 BAVENCIO treatments.

It is very important for you to keep all your appointments to receive BAVENCIO. If you miss an appointment, ask your doctor when 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 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 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
Lung problems (inflammation of the lungs)	<ul style="list-style-type: none"> • Breathing difficulties • Cough
Liver problems (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
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
Stomach problems (inflammation of the stomach)	<ul style="list-style-type: none"> • Stomach/abdomen pain or tenderness • Nausea • Vomiting
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
Hormone gland problems (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

<p>Type 1 diabetes, including increased acid in the blood produced from diabetes (diabetic ketoacidosis)</p>	<ul style="list-style-type: none"> • Feeling more hungry or thirsty than usual • Need 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
<p>Kidney problems (inflammation of the kidney)</p>	<ul style="list-style-type: none"> • Abnormal kidney function tests • Urinating less than usual • Blood in your urine • Swelling in your ankles
<p>Problems in other organs</p>	<p>Muscle problems (inflammation of muscle)</p> <ul style="list-style-type: none"> • Muscle pain • Weakness • Stiffness <p>Joint problems (inflammation of the joint)</p> <ul style="list-style-type: none"> • Joint pain • Stiffness • Swelling <p>Bile duct problems (inflammation and scarring of bile duct)</p> <ul style="list-style-type: none"> • Pain in the upper right part of the stomach • Fatigue • Itching • Yellowing of the skin or whites of eyes <p>Moisture-secreting glands problems</p> <ul style="list-style-type: none"> • Dry eyes • Dry mouth <p>Eye problems (inflammation of the eye)</p> <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) <p>Nervous system problems</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® (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 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.

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 BAVENCIO 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 immediately if you experience any side effects, including those not listed in this brochure.

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

Where to find further information

For more information, consult the BAVENCIO product information.

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

Reporting side effects

Please report side effects directly to your doctor.

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

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