



BAVE NCIO® T (avelumab)

PATIENT ALERT CARD

IMPORTANT - This card contains important safety information of your avelumab treatment. Keep this card with you during your treatment and for another 3 months after your last treatment with avelumab. Always show it to any healthcare professional involved in your treatment.

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. Local ADR Reporting Details: www.medicinesauthority.gov.mt/adportal or report to Vivian Corporation Ltd. on 22588600 or pv@viviancorp.com.

This educational material is part of the conditions of marketing authorisation and has been approved by the Malta Medicines Authority on 23rd of March 2022
Date of preparation March 2022

Avelumab

Important safety information to minimize 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 Vivian Corporation Ltd. on 22588600.

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 behavior, such as irritability or forgetfulness
- Feeling cold

- Very low blood pressure (fainting, dizziness, fatigue, nausea)

- Weight change
- Headache

Endocrine pancreas gland (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
- 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

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)

Nervous system

Guillain-Barre Syndrome:

- Pain
- Numbness
- Muscle weakness
- Difficulty walking

Myasthenia gravis, myasthenic syndrome:

- Muscle weakness

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: Local ADR Reporting Details: www.medicinesauthority.gov.mt/adrportal or report to Vivian Corporation Ltd on 22588600 or pv@viviancorp.com Ltd. By reporting side effects you can 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 producing glands (the thyroid, adrenal, pituitary and endocrine pancreas 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 available at www.ema.europa.eu/en/medicines/human/EPAR/bavencio

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, Guillain-Barre syndrome and myasthenia gravis, myasthenic syndrome.

Please consult the Summary of Product Characteristics for Avelumab at <https://www.ema.europa.eu/en/medicines/human/EPAR/bavencio> or call Vivian Corporation Ltd on 22588600 for more information.

IMPORTANT CONTACT

INFORMATION

Name of Specialist

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)