

KEYTRUDA[®] (pembrolizumab)

May cause some serious side effects which can sometimes become life-threatening and lead to death. These may happen any time during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

Contact your doctor right away if you develop any signs or symptoms including those not listed on this card. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of pembrolizumab or stop treatment with pembrolizumab.

For more information, consult the Package Leaflet for pembrolizumab containing information for the patient at www.ema.europa.eu.

IMPORTANT

- Do not attempt to treat side effects yourself.
- Do not stop your treatment with pembrolizumab unless you have discussed this with your doctor.
- **Take this card with you at all times**, especially when you travel, whenever you go to the emergency room, or when you must see another doctor.
- Be sure to notify any health care professional you see that you are being treated with pembrolizumab and show them this card.

Patient card

Lungs

- Shortness of breath
- Chest pain
- Coughing

Intestines

- Diarrhea or more bowel movements than usual
- Stools that are black, tarry, sticky, or contain blood or mucus
- Severe stomach pain or tenderness
- Nausea or vomiting

Liver

- Nausea or vomiting
- Feeling less hungry
- Pain on the right side of stomach
- Yellowing of skin or whites of eyes
- Dark urine
- Bleeding or bruising more easily than normal

Kidneys

- Changes in the amount or color of your urine

Hormone glands

- Rapid heartbeat
- Weight loss or weight gain
- Increased sweating
- Hair loss
- Feeling cold
- Constipation
- Deeper voice
- Muscle aches
- Dizziness or fainting
- Headaches that will not go away or unusual headache

Type 1 diabetes, including diabetic ketoacidosis

- Feeling more hungry or thirsty
- Needing to urinate more often
- Weight loss
- Feeling tired or feeling sick
- Stomach pain
- Fast and deep breathing
- Confusion
- Unusual sleepiness
- A sweet smell to your breath
- A sweet or metallic taste in your mouth
- A different odour to your urine or sweat

Reporting of side effects

If you get any side effects, talk to your doctor. You can also report side effects directly (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

Fimea: website: www.fimea.fi,
Lääkealan turvallisuus- ja kehittämiskeskus Fimea,
Lääkkeiden haittavaikutusrekisteri, PL 55, 00034 FIMEA

Marketing authorization holder:

finland.pharmacovigilance@merck.com or tel. (09) 804 650

Important Contact Information

Health care unit

Office Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name and Phone)

Important Information for Health Care Providers

This patient is being treated with pembrolizumab, which can cause immune-mediated adverse reactions that may appear any time during treatment or even after treatment. Assess patients for signs and symptoms of immune-mediated adverse reactions. Early diagnosis and appropriate management are essential to minimise any consequences of immune-mediated adverse reactions.

For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm etiology or exclude other causes. Based on the severity of the adverse reaction, withhold pembrolizumab and administer corticosteroids. Specific guidelines for managing immune-mediated adverse reactions are available in the Summary of Product Characteristics for pembrolizumab.

Consultation with an oncologist or other medical specialist may be helpful for management of organ-specific immune-mediated adverse reactions.

Please consult the Summary of Product Characteristics for pembrolizumab at www.ema.europa.eu or call Medical Information at (09) 804 650 for more information.