KEYTRUDA®
(pembrolizumab)

May cause some serious side effects. 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 KEYTRUDA or stop treatment with KEYTRUDA.

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

IMPORTANT

- Do not attempt to diagnose or treat side effects yourself.
- 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 KEYTRUDA and show them this 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
- Feeling more hungry or thirsty
- Needing to urinate more often
- Weight loss

Skin
- Rash
- Itching
- Skin blistering
- Peeling or sores
- Ulcers in mouth or in lining of nose, throat, or genital area

Other organs
- Eyes: changes in eyesight
- Muscles: pain or weakness
- Heart: shortness of breath, irregular heartbeat, feeling tired, or chest pain
- Pancreas: abdominal pain, nausea, and vomiting
- Nerves: temporary inflammation that causes pain, weakness, and paralysis in the arms and legs
- Rejection of a solid organ transplant after receiving pembrolizumab (tell your doctor if you have had a solid organ transplant)
- Immune disorder that can affect lungs, skin, eyes and/or lymph nodes
- Brain: inflammation that may cause confusion, fever, memory problems or seizures

Infusion reactions
- Shortness of breath
- Itching or rash
- Dizziness
- Fever

Complications in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)
- Skin rash
- Liver inflammation
- Abdominal pain
- Diarrhoea

MSD

▼ This medicinal product 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.

Important Contact Information

Name of Doctor	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 KEYTRUDA® (pembrolizumab), which can cause immune-related adverse reactions that involve the lungs, intestines, liver, kidneys, hormone glands, skin and other organs, as well as infusion-related reactions. Early diagnosis and appropriate management are essential to minimise any consequences of immune-related adverse reactions.

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

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

Assess patients for signs and symptoms of pneumonitis, colitis, hepatitis, nephritis, endocrinopathies (including hypophysitis, type 1 diabetes mellitus (including diabetic ketoacidosis), hypothyroidism and hyperthyroidism) and skin adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). Other immune-related adverse reactions reported in patients receiving KEYTRUDA include: uveitis, arthritis, myositis, myocarditis, pancreatitis, Guillain-Barré syndrome, solid organ transplant rejection following pembrolizumab treatment in donor organ recipients, myasthenic syndrome, haemolytic anaemia, sarcoidosis and encephalitis, as well as complications of allogeneic haematopoietic stem cell transplant.

Call for reporting

Please report suspected adverse reactions with any medicine or vaccine at: ADR Reporting; Website: www.medicinesauthority.gov.mt/adrportal

MSD