

KEYTRUDA® (pembrolizumab)

May cause some serious side effects.

Contact your doctor right away if you develop any of the signs or symptoms listed below. 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
- 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

Other organs

- Eyes: changes in eyesight
- Muscles: pain or weakness
- Pancreas: abdominal pain, nausea, and vomiting
- Skin: rash
- Nerves: temporary inflammation that causes pain, weakness, and paralysis in the arms and legs

Infusion reactions

- Shortness of breath
- Itching or rash
- Dizziness

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

- Fever

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, and other organs, as well as infusion-related reactions.

For suspected immune-related adverse reactions, ensure adequate evaluation to confirm etiology or exclude other causes. Based on the severity of the adverse reaction, withhold KEYTRUDA and administer corticosteroids. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Restart KEYTRUDA if the adverse reaction remains at Grade 1 or less within 12 weeks after last dose of KEYTRUDA and corticosteroid dose is ≤ 10 mg prednisone or equivalent per day. If any severe toxicity occurs a second time, permanently discontinue KEYTRUDA. Based

on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered. Specific guidelines for managing immune-related adverse reactions are available in the Summary of Product Characteristics for KEYTRUDA.

Please consult the Summary of Product Characteristics for KEYTRUDA at www.ema.europa.eu or call Medical Information

Assess patients for signs and symptoms of pneumonitis, colitis, hepatitis, nephritis, and endocrinopathies, including hypophysitis, type 1 diabetes mellitus (including diabetic ketoacidosis), hypothyroidism, and hyperthyroidism. Other immune-related adverse reactions reported in patients receiving KEYTRUDA include: uveitis, arthritis, myositis, pancreatitis, severe skin reactions, Guillain-Barré syndrome, myasthenic syndrome, hemolytic anemia, and partial seizures in a patient with inflammatory foci in brain parenchyma.



Call for reporting

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

Adverse events can also be reported to MSD Cyprus Ltd (tel. no. 8007 4433 in Malta).

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