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 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.

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▼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.

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

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)

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

Complications of stem cell transplant that uses donor stem cells (allogeneic) after treatment with KEYTRUDA.
These complications can be severe and can lead to death. Your doctor will monitor you for signs of these complications. Tell your transplant doctor that you have received pembrolizumab in the past.

Important Contact Information

Name of Doctor	Office Phone	After-hours Phone

My Name	My Phone	After-hours 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.

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. Consider to 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. The safety of re-initiating KEYTRUDA in patients previously experiencing immune-related myocarditis is not known. Permanently discontinue for Grade 3 or 4 myocarditis. Permanently discontinue KEYTRUDA if any Grade ≥3 toxicity occurs a second time and for any Grade 4 immune-related adverse reaction toxicity, except for endocrinopathies that are controlled with replacement hormones or haematological toxicity, only in patients with classical Hodgkin lymphoma, in whom KEYTRUDA should be withheld until adverse reactions recover to Grade 0-1. 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 at 8007 4433 for more information.

Assess patients for signs and symptoms of pneumonitis, colitis, hepatitis, nephritis, and endocrinopathies, including hypophysitis, type 1 diabetes mellitus (including diabetic ketoacidosis), hypothyroidism, 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, hemolytic anemia, and partial seizures in a patient with inflammatory foci in brain parenchyma, . as well as potential complications of haematopoietic allogeneic stem cell transplant in classical Hodgkin lymphoma. **Call for reporting:** Please report suspected adverse reactions with any medicine or vaccine at: ADR Reporting; Website: www.medicinesauthority.gov.mt/adrportal

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Last revised Dec 2017. For more information please contact MSD in Cyprus at 80000 673 www.msd-cyprus.com.cy or malta_info@merck.com