

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 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.

Important Safety Information

Patient Alert 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

▼ 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.



MSD

Revision Date : 17 Oct 2019, Revision No. 12

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 may appear any time during treatment or even after treatment. Assess patients for signs and symptoms of immune-related adverse 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.

Carry this card for at least 4 months after the last dose of pembrolizumab.

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

Revision Date : 17 Oct 2019

Revision No. 12



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In case you need any update or you have an inquiry or need to report an adverse reaction, you can contact:

Tel: +966 11 2506700 Fax: +966 11 4006484 Email: DPDC.SAUDI@MERCK.COM

MSD Building #3, Business Gate, Airport Road, Qurtubah, Riyadh 13244PO Box 17098 Saudi Arabia

For extra copies please contact:

Tel: +966 11 2506700

To report any side effect(s) in Saudi Arabia:

The National Pharmacovigilance Centre (NPC), at SFDA:

o Fax: +966-11-205-7662

o Call NPC at +966-11-20382222, Exts: 2317-2356-2353-2354-2334-2340.

o Toll free phone: 8002490000

o E-mail: npc.drug@sfd.gov.sa

o Website: www.sfd.gov.sa/npc