

## Important Safety Information

# Your Guide to **KEYTRUDA<sup>®</sup>** (pembrolizumab)

## Information for Patients

- ▼ 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.



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# Introduction

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Your doctor has prescribed KEYTRUDA® (pembrolizumab) to treat your cancer. Please refer to the Patient Leaflet to read what KEYTRUDA is and what it is used for. This brochure will serve as a guide to your treatment, including what to expect while you are taking KEYTRUDA.

This guide will explain some of the side effects that might occur during or after treatment with KEYTRUDA, and how to check for them. In some cases, symptoms may be delayed, and may develop after your last dose. You will also learn why it is important to report any symptoms to your doctor right away.



# About KEYTRUDA<sup>®</sup> (pembrolizumab)

**KEYTRUDA is a medicine used to treat your cancer.**

Treatment with **pembrolizumab** may have side effects. **Pembrolizumab** is a type of therapy that works by helping your immune system fight your cancer.

## Before you start KEYTRUDA

Tell your doctor about any medicines you are taking, have recently taken, or might take.

Make sure your doctor knows if you:

- Have an autoimmune disease (a condition where the body attacks its own cells).
- Have pneumonia or inflammation of the lungs (called pneumonitis).
- Were previously given ipilimumab, another medicine for treating a selected type of cancer, and experienced serious side effects because of that medicine.
- Had an allergic reaction to other monoclonal antibody therapies.
- Have or have had chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV).
- Have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS).
- Have liver damage.
- Have kidney damage.
- Have had a solid organ transplant or a bone marrow (stem cell) transplant that used donor stem cells (allogeneic).
- Are taking other medicines that make your immune system weak. Examples of these may include corticosteroids, such as prednisone.
- Are taking, have recently taken, or might take any other medicines.
- Are pregnant, think you may be pregnant, or are planning to have a baby.
- Are a woman who could become pregnant, you must use adequate birth control while you are being treated with **pembrolizumab** and for at least 4 months after your last dose.
- Are breast-feeding or plan to breast-feed.

# What you should know about your treatment

## How you are given KEYTRUDA® (pembrolizumab)

**Pembrolizumab** will be given to you in a hospital or clinic under the supervision of an experienced doctor. Your doctor will give you **pembrolizumab** through an infusion into a vein.

The infusion will last for 30 minutes. Please refer to the Patient Leaflet for the recommended dose of **pembrolizumab**.

**KEYTRUDA is usually given once every 3 or 6 weeks. Your doctor will decide how many treatments you need.**

Sometimes the tumor may get bigger for the first few months before it starts to shrink or new tumors may appear. If your tumor seems to get worse at first after starting treatment with **pembrolizumab**, your doctor may continue your treatment if your health is stable, and will check again to see if you are responding.

It is important that you visit your doctor for your scheduled appointments, so your doctor can check your progress and administer **pembrolizumab**. If you are unable to keep an appointment, call your doctor right away to reschedule.

If you stop or interrupt your treatment, it may stop the effect of the medicine. Don't stop your treatment with **pembrolizumab** unless you have discussed this with your doctor.

## Possible side effects

Like all medicines, **pembrolizumab** can cause side effects, although not everyone gets them. When you take **pembrolizumab**, you can have some serious side effects. These side effects can sometimes become life-threatening and can lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time. It is very important to tell your doctor about any symptoms you notice while taking **pembrolizumab**. 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 your treatment with **pembrolizumab**.

# Tell your doctor right away if you have any of these symptoms

Side effect	Signs or symptoms
Lung problems (inflammation of the lungs)	<ul style="list-style-type: none"> <li>• Shortness of breath</li> <li>• Chest pain</li> <li>• Coughing</li> </ul>
Intestinal problems (inflammation of the intestines)	<ul style="list-style-type: none"> <li>• Diarrhoea or more bowel movements than usual</li> <li>• Stools that are black, tarry, sticky, or contain blood or mucus</li> <li>• Severe stomach pain or tenderness</li> <li>• Nausea or vomiting</li> </ul>
Liver problems (inflammation of the liver)	<ul style="list-style-type: none"> <li>• Nausea or vomiting</li> <li>• Feeling less hungry</li> <li>• Pain on the right side of the stomach</li> <li>• Yellowing of your skin or whites of eyes</li> <li>• Dark urine</li> <li>• Bleeding or bruising more easily than normal</li> </ul>
Kidney problems (inflammation of the kidney)	<ul style="list-style-type: none"> <li>• Changes in the amount or color of your urine</li> </ul>
Hormone gland problems (especially thyroid, pituitary, adrenal)	<ul style="list-style-type: none"> <li>• Rapid heart beat</li> <li>• Weight loss or weight gain</li> <li>• Increased sweating</li> <li>• Hair loss</li> <li>• Feeling cold</li> <li>• Constipation</li> <li>• Deeper voice</li> <li>• Muscle aches</li> <li>• Dizziness or fainting</li> <li>• Headaches that will not go away or unusual headache</li> </ul>
Type 1 diabetes	<ul style="list-style-type: none"> <li>• Feeling more hungry or thirsty</li> <li>• Needing to urinate more often</li> <li>• Weight loss</li> </ul>

If you have any side effects, including any possible side effects not listed here, contact your doctor.

# Watching for side effects

## It is important to be aware of symptoms

If you notice any symptoms while receiving KEYTRUDA® (pembrolizumab), you should talk to your doctor right away. Be aware that side effects may still occur after receiving your last dose of pembrolizumab.

Certain medications, such as corticosteroids, may be used to prevent more severe complications and reduce your symptoms. Your doctor may delay or completely stop your treatment if your side effects are too severe.

Do not attempt to diagnose or treat side effects yourself.

## What to do if symptoms occur when you are away from home

It is important that you contact your doctor whenever symptoms occur. **Always carry your Alert Card for KEYTRUDA** with your doctor's contact information so that he or she may be reached in case of emergency. The Alert Card contains important information about symptoms that need to be reported immediately to the doctor or nurse treating you while you are away from home. It also alerts other doctors that you are being treated with pembrolizumab.

**Please contact your doctor if you have any questions about KEYTRUDA or how it works.**

**Carry your Alert Card for KEYTRUDA with you at all times.**

# Remember

KEYTRUDA® (pembrolizumab) is a type of therapy that works by helping your immune system fight your cancer. This type of therapy can sometimes have side effects.

**Pembrolizumab** is given through an infusion into your vein over 30 minutes, usually every 3 or 6 weeks.

With **pembrolizumab**, certain side effects can occur that may be serious and may happen anytime during treatment or even after your treatment has ended.

**Contact your doctor right away if you experience any side effects. This includes any possible side effects not listed in the package leaflet.**

**Speak with your doctor if you have any questions about KEYTRUDA or how it works.**

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

**For extra copies please contact:**

**Tel: +966 11 2506700**

**To report any side effect(s):**

**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@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)

o Website: [www.sfda.gov.sa/npc](http://www.sfda.gov.sa/npc)



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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: [DPOC.SAUDI@MERCK.COM](mailto:DPOC.SAUDI@MERCK.COM)**

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