

Your Guide to **KEYTRUDA[®]** (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.



Introduction

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 while you undergo treatment with KEYTRUDA, and how to check for them. You will also learn why it is important to report any symptoms to your doctor right away.



About KEYTRUDA[®] (pembrolizumab)

KEYTRUDA is a medicine used to treat your cancer.

Treatment with KEYTRUDA may have side effects. KEYTRUDA 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 KEYTRUDA 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)

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

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

KEYTRUDA is usually given once every 3 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 KEYTRUDA, 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 KEYTRUDA. If you are unable to keep an appointment, call your doctor right away to reschedule.

Possible side effects

Like all medicines, KEYTRUDA can cause side effects, although not everyone gets them. When you take KEYTRUDA, you can have some serious side effects. 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 KEYTRUDA. 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 your treatment with KEYTRUDA.

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

Side effect	Signs or symptoms
Lung problems (inflammation of the lungs, possibly fatal)	<ul style="list-style-type: none"> • Shortness of breath • Chest pain • Coughing
Intestinal problems (inflammation of the intestines)	<ul style="list-style-type: none"> • Diarrhoea 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 problems (inflammation of the liver)	<ul style="list-style-type: none"> • Nausea or vomiting • Feeling less hungry • Pain on the right side of the stomach • Yellowing of your skin or whites of eyes • Dark urine • Bleeding or bruising more easily than normal
Kidney problems (inflammation of the kidney)	<ul style="list-style-type: none"> • Changes in the amount or color of your urine
Hormone gland problems (especially thyroid, pituitary, adrenal)	<ul style="list-style-type: none"> • Rapid heart beat • 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	<ul style="list-style-type: none"> • Feeling more hungry or thirsty • Needing to urinate more often • Weight loss
Skin problems (inflammation of the skin, possibly fatal)	<ul style="list-style-type: none"> • Rash • Itching • Skin blistering • Peeling or sores • Ulcers in mouth or in lining of nose, throat, or genital area
Problems in other organs	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Shortness of breath • Itching or rash • Dizziness • Fever

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

Complications, including graft-versus-host-disease, in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be severe and can lead to death. They may occur if you had this kind of transplant in the past or if you get it in the future. Your doctor will monitor you for signs and symptoms, which may include skin rash, liver inflammation, abdominal pain, or diarrhoea.

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.

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 KEYTRUDA.

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

Don't miss an appointment for treatment with KEYTRUDA® (pembrolizumab)

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

Please try your best to keep all of your appointments, and reschedule as soon as possible if you miss one. **Contact your doctor immediately if you experience any side effects, including those not listed in this brochure.**

Your tumor may first grow in size or new ones may appear before the positive effects of KEYTRUDA begin to occur. It is important that you receive KEYTRUDA as prescribed to get the most out of your treatment.

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

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.

KEYTRUDA is given through an infusion into your vein over 30 minutes, usually every 3 weeks.

With KEYTRUDA, certain side effects can occur that may be serious.

Contact your doctor right away if you experience any side effects.

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

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to ADR Reporting at: www.medicinesauthority.gov.mt/adrportal, or alternatively to Merck Sharp & Dohme Cyprus Ltd by calling **800 7 4433** or at **malta_info@merck.com**. By reporting side effects you can help provide more information on the safety of this medicine.



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