

Your guide to

KEYTRUDA[®]

(Pembrolizumab)

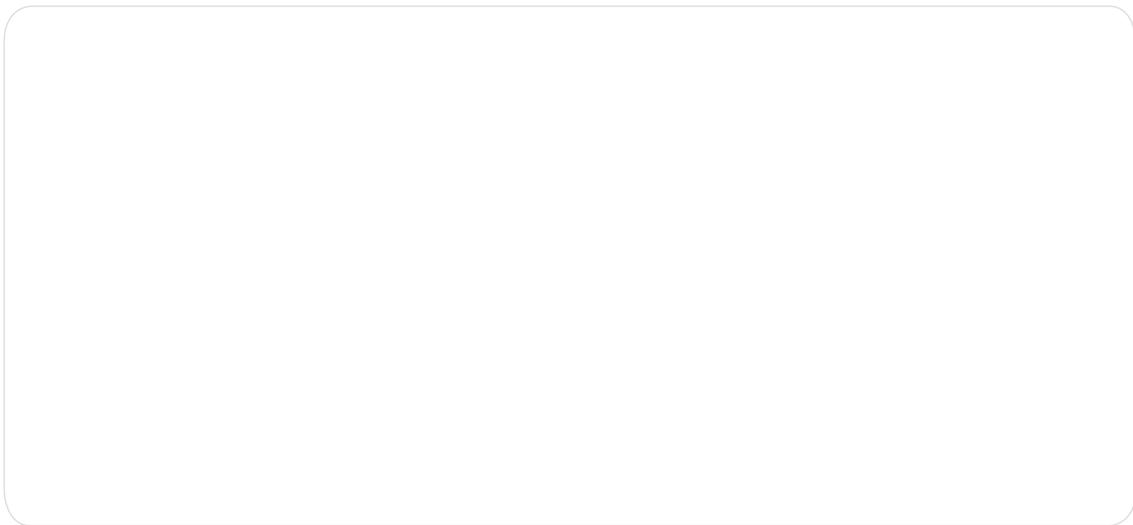
Information for Patients

- ▼ This medicine 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 Information Leaflet to read what KEYTRUDA® is and what it is used for. This brochure will serve as a guide to your treatment, including what you should know and expect during treatment with KEYTRUDA®.

This guide describes some side effects that may occur during treatment with KEYTRUDA® and how to check for them. It will also help you to understand why it is important to report any signs of illness to your doctor right away.



Doctor's stamp

About KEYTRUDA® (pembrolizumab)

KEYTRUDA® is a medicine to treat your cancer.

Treatment with KEYTRUDA® may have side effects. KEYTRUDA® is a medicine that helps your immune system to fight your cancer.

Before starting treatment with KEYTRUDA®

Tell your doctor about any medicines you are taking/using, have recently taken/used or might take/use. Talk to your doctor if you:

- Have an autoimmune disease (a condition where the body attacks its own cells).
- Have pneumonia or an inflammation of your lungs (called pneumonitis).
- Were previously given ipilimumab, another medicine for treating a certain 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 transplant that used donor stem cells (allogeneic stem cell transplant).
- Are using other medicines that make your immune system weak. Examples of these may include corticosteroids, such as prednisone.
- Are using/taking, have recently used/taken or might use/take any other medicines.
- Are pregnant, think you may be pregnant or are planning to have a baby.
- If you are a woman who could become pregnant, you must use reliable birth control while you are being treated with KEYTRUDA® and for at least four months after your last dose of KEYTRUDA®.
- 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. Our doctor will give you KEYTRUDA® through an infusion into a vein (IV).

The infusion will last for 30 minutes. Please consult the Patient Information Leaflet for the recommended dose of KEYTRUDA®.

KEYTRUDA® is usually given 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 to the treatment.

It is important that you visit your doctor for your scheduled appointments so your doctor can check your progress and give you 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 everybody gets them. When you get KEYTRUDA®, you can have some serious side effects. You can have more than one side effect at the same time. It is very important that you tell your doctor about any signs of illness you experience during treatment with KEYTRUDA®. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may delay the next dose of KEYTRUDA® or stop your treatment with KEYTRUDA®.

Tell your doctor right away if you notice any of the following ...

... signs or 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"> • Diarrhea, more bowel movements than usual • Black, tarry, sticky stools or stools with 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 your stomach • Yellowing of your skin or whites of eyes • Dark urine • Bleeding or bruising more easily than normal
Kidney problems (inflammation of the kidneys)	<ul style="list-style-type: none"> • Changes in the amount or color of your urine
Type 1 diabetes	<ul style="list-style-type: none"> • Feeling more hungry or thirsty than usual • Need to urinate more often • Weight loss
Reactions related to the infusion	<ul style="list-style-type: none"> • Shortness of breath • Itchiness or rash • Dizziness • Fever
Hormone gland problems (especially the thyroid, pituitary and adrenal glands)	<ul style="list-style-type: none"> • 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
Skin problems (inflammation of the skin, possibly fatal)	<ul style="list-style-type: none"> • Rash • Itching • Blistering • Peeling or sores • Ulcers in the mouth or lining of the 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, chest pain • Pancreas: abdominal pain, nausea and vomiting • Nerves: temporary inflammation that causes pain, weakness and paralysis in the arms and legs • Solid organ transplant rejection following administration of pembrolizumab (please talk to your doctor if you have had a solid organ transplant) • An immune disorder that can affect the lungs, skin, eyes and/or lymph nodes (sarcoidosis) • Inflammation of the brain, which may include confusion, fever, memory problems or seizures (encephalitis)

Tell your doctor immediately if you notice any of the following ...

... signs or symptoms

Complications, including graft versus host disease (GVHD), in people with a bone marrow transplant that uses donor stem cells (allogeneic stem cell transplant).

These complications may be severe and may 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, and diarrhea.

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

Watching for side effects

It is important to notice and recognize signs and 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 the next dose of KEYTRUDA® or stop your treatment with KEYTRUDA® 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 KEYTRUDA® Patient Alert Card** with your doctor's contact information so that he or she may be reached in an emergency.

The Patient Alert Card contains important information about signs and 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®.

Don't miss an appointment for treatment with

KEYTRUDA® (pembrolizumab)

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

Try your best to keep all of your appointments with the doctor and reschedule as soon as possible if you miss one.

Contact your doctor right away if you experience any side effects, including those not listed in this brochure.

Your tumor may first grow in size or new tumors may appear before the positive effects of KEYTRUDA® start to show. 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.

Carry your KEYTRUDA® Patient Alert Card with you at all times.

Remember

KEYTRUDA® (pembrolizumab) is a medicine that helps your immune system to fight your cancer. This type of treatment can sometimes have side effects.

KEYTRUDA® is given through an approximately 30-minute infusion into your vein, 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.

This information is an unofficial translation by a certified translation agency of the German documents, which contain legally required information.

Bei dieser Information handelt es sich um eine nicht-amtliche Übersetzung der beauftragten deutschsprachigen Unterlagen durch ein zertifiziertes Übersetzungsbüro.



MSD SHARP & DOHME GMBH
Lindenplatz 1, 85540 Haar, www.msd.de