Your guide to

KEYTRUDA®

(Pembrolizumab)

Information for patients

▼ This medicine is subject to additional monitoring.
This will allow a quick identification of new safety information. You can help by reporting any side effects you may get (see last page of this booklet).

MSD

Doctor’s stamp

Introduction

Your doctor has prescribed KEYTRUDA® (pembrolizumab) to treat your cancer. Please refer to the Patient Information Leaflet to see what KEYTRUDA® is and what it is used for. This booklet 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 or after treatment with KEYTRUDA® and how to check for them. In some cases, the signs of illness may be delayed and will occur only after you have received your last dose. It will also help you understand why it is important to report any signs of illness to your doctor right away.

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 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.
- Have had an allergic reaction after taking treatments containing other monoclonal antibodies.
- 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 of childbearing potential, 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. Your 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 or 6 weeks. Your doctor will decide how many treatments you need.

Sometimes the tumor can get bigger for the first few months before it starts to shrink or new tumors may occur. 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.

Canceling or interrupting your treatment may reduce the effect of this medicine. Do not stop your treatment with KEYTRUDA® before talking to your doctor about it.

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. These side effects can sometimes be life-threatening and can even lead to death. These side effects can occur at any time during treatment or even after your treatment has stopped. You may even suffer 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 serious 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)**	• Shortness of breath • Chest pain • Cough
Intestinal problems **(inflammation of the intestine)**	• 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)**	• 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 than normal
Kidney problems **(inflammation of the kidneys)**	• Changes in the amount or color of your urine
Endocrine problems **(especially the thyroid, pituitary and adrenal 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

Side effect	Signs or symptoms
Type I diabetes	• Increased hunger or thirst • More frequent urination • Weight loss

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 of illness and symptoms

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

Certain medicines, such as corticosteroids, may be used to prevent more serious 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 of illness 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®.

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 or 6 weeks.

With KEYTRUDA®, certain potentially serious side effects may occur at any time during the treatment or even after the treatment has stopped.

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

Contact your doctor right away if you experience any side effects. This includes any possible side effects not listed in the Patient Information Leaflet.

Reporting of side effects
You can also report side effects directly to the Paul Ehrlich Institute,
Paul-Ehrlich-Str. 51-59, 63225 Langen, Germany
Phone: +49 6103 77 0, Fax: +49 6103 77 1234
Website: www.pei.de or to
MSD SHARP & DOHME GMBH
Drug Safety Department, Lindenplatz 1, 85540 Haar, Germany
Fax: +49 89 4561 13 52
E-Mail: arzeimittelsicherheit@msd.de

By reporting side effects you can help provide more information on the safety of this medicine.

This information is an unofficial translation
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Bei dieser Information handelt es sich um eine nicht- amtliche Übersetzung der beauflagten deutschsprachigen Unterlagen durch ein zertifiziertes Übersetzungsbüro.

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