

Your Guide to
KEYTRUDA[®]
(pembrolizumab)

Important safety information to minimise the risk of immune-related adverse reactions

Information for Patients

Introduction

Your doctor has prescribed KEYTRUDA® (pembrolizumab) to treat your cancer. Please refer to the Patient Information Leaflet to read what pembrolizumab 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 this medicine.

This guide will explain some of the side effects that might occur during or after treatment with pembrolizumab, 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.

Glue
Alert Card
Here

DOCTOR STAMP

About pembrolizumab

Pembrolizumab is a medicine used to treat some types of cancer.

This treatment may have side effects. Pembrolizumab is a type of therapy that works by helping your immune system fight your cancer.

Before you start pembrolizumab

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 (allogenic)
- 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 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 Information Leaflet for the recommended dose of pembrolizumab.

Sometimes the tumour may get bigger for the first few months before it starts to shrink or new tumours may appear. If your tumour 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.

Stopping your treatment may stop the effect of the medicine. Do not stop treatment with pembrolizumab unless you have discussed this with your doctor. If you have any further questions about your treatment, ask your doctor.

Pembrolizumab can cause serious side effects that need to be treated straight away

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.

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"> • 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 colour 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

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 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** 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 pembrolizumab or how it works.

Carry your Alert Card with you at all times.

Remember

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 pembrolizumab or how it works.

Where to find further information

For more information, consult the KEYTRUDA Patient Information Leaflet (PIL) at www.medicines.org.uk/emc or call MSD Medical Information on Tel: 01992 467272.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Reporting side effects

Please report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD on Tel: 01992 467272. By reporting side effects you can help provide more information on the safety of this medicine.



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Patient Alert Card

KEYTRUDA®
(pembrolizumab)

Important safety information to minimise the risk of immune-related adverse reactions

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 specialist 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 pembrolizumab or stop treatment.

For further information, consult the Patient Information Leaflet (PIL) at www.medicines.org.uk/emc or call MSD Medical Information on Tel: 01992 467272.

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 Accident and Emergency department, or when you must see another doctor
- Carry this card for at least 4 months after the last dose of pembrolizumab.
- Be sure to notify any health care professional you see that you are being treated with pembrolizumab and show them this card
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD on Tel: 01992 467272. By reporting side effects you can help provide more information on the safety of this medicine

Lungs

- Shortness of breath
- Chest pain
- Coughing

Intestines

- 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

- 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 colour of your urine

Hormone glands

- Rapid heartbeat
- Weight loss or 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

Important Contact Information

Name of Specialist

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (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 pembrolizumab and administer corticosteroids. **Specific guidelines for managing immune-related adverse reactions are available in the Summary of Product Characteristics for pembrolizumab.**

Consultation with an oncologist or other medical specialist may be helpful for management of organ-specific immune-related adverse reactions.

Please consult the Summary of Product Characteristics for KEYTRUDA at www.medicines.org.uk/emc or call MSD Medical Information on Tel: 01992 467272 for more information.

