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

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. See www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store for how to report side effects. Adverse events should also be reported to MSD on Tel: 01992 467272.
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 while you undergo treatment with pembrolizumab, and how to check for them. You will also learn why it is important to report any symptoms to your doctor right away.
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
- 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.

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. 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

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Signs or symptoms</th>
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| Lung problems (inflammation of the lungs, possibly fatal) | • Shortness of breath  
• Chest pain  
• Coughing |
| Intestinal problems (inflammation of the 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 problems (inflammation of the liver)             | • 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)           | • Changes in the amount or colour of your urine |
| Hormone gland problems (especially thyroid, pituitary, adrenal) | • 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                                      | • Feeling more hungry or thirsty  
• Needing to urinate more often  
• Weight loss |
| Skin problems (inflammation of the skin, possibly fatal) | • Rash  
• Itching  
• Skin blistering  
• Peeling or sores  
• Ulcers in mouth or in lining of nose, throat, or genital area |
| Problems in other organs                             | • 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) |
| Infusion reactions                                   | • Shortness of breath  
• Itching or rash  
• Dizziness  
• Fever |

Complications of stem cell transplant that uses donor stem cells (allogeneic) after treatment with pembrolizumab. These complications can be severe and can lead to death. Your doctor will monitor you for signs of these complications. Tell your transplant doctor that you have received pembrolizumab in the past.

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 the final 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.

Carry your Alert Card with you at all times.
Don’t miss an appointment for treatment with pembrolizumab

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.

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

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

Pembrolizumab is a type of therapy that works by helping your immune system fight your cancer. Pembrolizumab is given through an infusion into your vein over 30 minutes, usually every 3 weeks. This type of therapy can sometimes have side effects.

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