Your Guide to **KEYTRUDA SC™** (pembrolizumab)

Solution for Injection
165 mg/mL

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



MSD

Information for Patients

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this brochure.

Introduction

Your doctor has prescribed KEYTRUDA SC (pembrolizumab) to treat your cancer.

KEYTRUDA SC may be given in combination with other anti-cancer medicines with or without radiation therapy. If you have any questions about these medicines, please ask your doctor.

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 KEYTRUDA SC, 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 SC
(pembrolizumab)

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



Before you start KEYTRUDA SC

Tell your doctor about any medicines that you are taking, have recently taken, or might take.

Make sure your doctor knows if you:

- Have any pre-existing medical condition
- Were previously given YERVOY® (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
- 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 SC and for at least 4 months after your last dose
- Are breast-feeding or plan to breast-feed. Do not breast-feed during treatment with KEYTRUDA SC.



What you should know about your treatment

How you are given KEYTRUDA SC



KEYTRUDA SC will be given to you in a hospital or clinic under the supervision of an experienced doctor. KEYTRUDA SC will be administered as an injection under the skin, in the stomach area (abdomen) or thigh, over about 1-2 minutes.



Your doctor may switch your treatment from KEYTRUDA (infusion into your vein) to KEYTRUDA SC (injection under the skin) or KEYTRUDA SC to KEYTRUDA.



Most people get KEYTRUDA SC every 3 weeks or 6 weeks, depending on the dose you are given. Your doctor will decide how many treatments you need.





Sometimes the tumour may get bigger, in the first few months after starting treatment with KEYTRUDA SC, before it starts to shrink or new tumours may appear. Your doctor may continue your treatment if your health condition 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 SC. If you are unable to keep an appointment, call your doctor right away to reschedule.

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

Possible side effects

Local injection-site reactions such as redness, bleeding, skin thickening and pain have been commonly reported when KEYTRUDA is administered subcutaneously.

Like all medicines, KEYTRUDA SC can cause side effects, although not everyone gets them. When you take KEYTRUDA SC, you can have some serious side effects that need to be treated straight away. 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. It is very important to tell your doctor about any symptoms you notice while taking KEYTRUDA SC. 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 SC or stop your treatment.

Tell your doctor as soon as it is possible if you have any of these symptoms

Side effects



Lung problems
(inflammation of the lungs)

Signs or symptoms
- Shortness of breath
- Chest pain
- Coughing



Intestinal problems
(inflammation of the intestines)

Signs or symptoms
- 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)

Signs or symptoms
- 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)

Signs or symptoms
- Changes in the amount or colour of your urine



Hormone gland problems
(especially thyroid, pituitary, adrenal glands)

Signs or symptoms
- 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



Type 1 diabetes

Signs or symptoms
- Feeling more hungry or thirsty
- Needing to urinate more often
- Weight loss



Skin problems

Signs or symptoms
- Rash
- Itching
- Skin blistering, peeling or sores
- Ulcers in mouth or in lining of nose, throat, or genital area



Problems in other organs

Signs or symptoms
- Eyes: changes in eyesight
- Muscles: pain or weakness
- Nerves: temporary inflammation that causes pain, weakness and paralysis in the arms and legs
- Pancreas: abdominal pain, nausea, and vomiting
- Heart: shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis, pericarditis)
- Swollen lymph nodes, rash or tender lumps on skin, cough or eye pain (sarcoidosis)
- Brain inflammation that may cause confusion, fever, memory problems or seizures (encephalitis)
- Pain, numbness, tingling, or weakness in the arms or legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation (myelitis)
- Inflammation of the blood vessels (vasculitis)
- Decreased function of the parathyroid gland, which may include muscle cramps or spasms, fatigue and weakness (hypoparathyroidism)
- Inflammation and scarring of the bile ducts, which may present as pain in the upper right part of the stomach, swelling of the liver or spleen, fatigue, itching, or yellowing of the skin or the whites of eyes (sclerosing cholangitis)
- Inflammation of the stomach lining, which may include severe stomach pain or tenderness, nausea or vomiting (gastritis)
- Destruction of red blood cells, which may include dark urine, pale or yellow skin/eyes, lightheadedness, feeling tired, rapid heartbeat, or shortness of breath (hemolytic anemia)
- Insufficient production of new blood cells, which may lead to fatigue, shortness of breath or dizziness (aplastic anaemia)
- Decreased ability of the pancreas to make digestive enzymes, which may include diarrhea with loose and oily stools, weight loss, metabolic bone disease, and vitamin or mineral deficiencies (exocrine pancreatic insufficiency)
- A condition in which some or all of the following happen together: muscle pain or weakness, changes in eyesight, feeling tired, shortness of breath, chest pain, or irregular heartbeat (myocarditis-myositis-myasthenia gravis overlap syndrome)



Infusion reactions

Signs or symptoms
- Shortness of breath
- Itching or rash
- Dizziness
- Fever

There are possible side effects of treatment with KEYTRUDA SC in people who have received a transplant

- **Rejection of a transplanted organ.** People who have had an organ transplant may have an increased risk of organ transplant rejection. Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

- **Complications, including graft-versus-host-disease (GVHD) in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications may occur if you underwent transplantation either before or after being treated with KEYTRUDA SC. These complications can be severe and can lead to death. Your doctor will monitor you for the following signs and symptoms: skin rash, liver inflammation, abdominal pain, and diarrhoea.

Watching for side effects

It is important to be aware of symptoms

If you notice any symptoms while receiving KEYTRUDA SC, including any side effects not listed in this brochure, you should talk to your doctor right away. Be aware that side effects may still occur after receiving the final dose of KEYTRUDA SC.

Certain medications, such as corticosteroids, may be used to prevent more severe complications and reduce your symptoms. Your doctor may delay or completely stop KEYTRUDA SC treatment if your side effects are too severe.

Do not attempt to diagnose or treat side effects yourself.





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