

Your Guide to **KEYTRUDA[®]** (pembrolizumab)

25 mg/mL Solution for Infusion

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



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 (pembrolizumab) to treat your cancer.

KEYTRUDA 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, 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

(pembrolizumab)

KEYTRUDA 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

Tell your doctor about any medicines that 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 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
- ◆ 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
- ◆ Are taking other medicines that make your immune system weak. Examples of these include corticosteroids such as prednisolone
- ◆ 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 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.



What you should know about your treatment

How you are given KEYTRUDA

KEYTRUDA will be given to you in a hospital or clinic under the supervision of an experienced doctor. KEYTRUDA will be administered through an infusion into a vein.



The infusion will last for 30 minutes.



KEYTRUDA is usually given once 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, 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. 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 everyone gets them. When you take KEYTRUDA, 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. 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 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)



Infusion reactions

Signs or symptoms

- ◆ Shortness of breath
- ◆ Itching or rash
- ◆ Dizziness
- ◆ Fever

There are possible side effects of treatment with KEYTRUDA 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. 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.

The following side effects have been reported:



Very common

(may affect more than 1 in 10 people)

KEYTRUDA alone	KEYTRUDA in combination with chemotherapy or chemoradiotherapy	KEYTRUDA in combination with axitinib or lenvatinib
❖ decrease in the number of red blood cells ❖ reduced thyroid gland activity ❖ feeling less hungry ❖ headache ❖ shortness of breath; cough ❖ diarrhoea; stomach pain; nausea; vomiting; constipation ❖ itching; skin rash ❖ pain in muscle and bones; joint pain ❖ feeling tired; unusual tiredness or weakness; swelling; fever	❖ decrease in the number of red blood cells; decreased number of white blood cells (neutrophils); decrease in the number of platelets (bruising or bleeding more easily) ❖ reduced thyroid gland activity ❖ decreased potassium in the blood; feeling less hungry ❖ trouble sleeping ❖ inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs; headache; dizziness ❖ shortness of breath; cough ❖ diarrhoea; nausea; vomiting; stomach pain; constipation ❖ hair loss; itching; skin rash ❖ pain in the muscles and bones; joint pain ❖ feeling tired; unusual tiredness or weakness; fever; swelling ❖ increased blood level of the liver enzyme alanine aminotransferase; increased blood level of the liver enzyme aspartate aminotransferase; abnormal kidney function test	❖ urinary infections (increased frequency in urination and pain in passing urine) ❖ decrease in the number of red blood cells ❖ reduced thyroid gland activity ❖ feeling less hungry ❖ headache; change in your sense of taste ❖ high blood pressure ❖ shortness of breath; cough ❖ diarrhoea; stomach pain; nausea; vomiting; constipation ❖ skin rash; itching ❖ joint pain; pain in the muscles and bones; muscle pain, aches or tenderness; pain in arms or legs ❖ feeling tired; unusual tiredness or weakness; swelling; fever ❖ increased levels of lipase, an enzyme that breaks down fats; increased blood level of the liver enzyme alanine aminotransferase; increased blood level of the liver enzyme aspartate aminotransferase; abnormal kidney function test



Common

(may affect up to 1 in 10 people)

KEYTRUDA alone	KEYTRUDA in combination with chemotherapy or chemoradiotherapy	KEYTRUDA in combination with axitinib or lenvatinib
✦ lung infection ✦ decrease in the number of platelets (bruising or bleeding more easily); decreased number of white blood cell (neutrophils; lymphocytes) ✦ reaction related to the infusion of the medicine ✦ overactive thyroid gland; hot flush ✦ decreased sodium, potassium or calcium in the blood ✦ trouble sleeping ✦ dizziness; inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs; lack of energy; change in your sense of taste ✦ dry eye ✦ abnormal heart rhythm ✦ high blood pressure ✦ inflammation of the lungs ✦ inflammation of the intestines; dry mouth ✦ inflammation of the liver ✦ red raised rash, sometimes with blisters; inflammation of the skin; patches of skin which have lost colour; dry, itchy skin; hair loss; acne-like skin problem ✦ muscle pain, aches or tenderness; pain in arms or legs; joint pain with swelling ✦ flu-like illness; chills ✦ increased blood level of the liver enzyme alanine aminotransferase; increased blood level of the liver enzyme aspartate aminotransferase; increased blood level of the liver enzyme alkaline phosphatase; increased calcium in the blood; increased bilirubin in the blood; abnormal kidney function test	✦ lung infection ✦ decreased number of white blood cells (neutrophils) with a fever; decreased number of white blood cells (leukocytes, lymphocytes) ✦ reaction related to the infusion of the medicine ✦ decreased secretion of hormones produced by the adrenal glands; overactive thyroid gland; inflammation of the thyroid ✦ decreased sodium or calcium in the blood ✦ change in your sense of taste; lack of energy ✦ dry eye ✦ abnormal heart rhythm ✦ high blood pressure ✦ inflammation of the lungs ✦ inflammation of the intestines; inflammation of the stomach; dry mouth ✦ inflammation of the liver ✦ red raised rash, sometimes with blisters; inflammation of the skin; acne-like skin problem; dry, itchy skin ✦ muscle pain, aches or tenderness; pain in arms or legs; joint pain with swelling ✦ sudden kidney damage ✦ flu-like illness; chills ✦ increased bilirubin in the blood; increased blood level of the liver enzyme alkaline phosphatase; increased calcium in the blood	✦ lung infection ✦ decreased number of white blood cells (neutrophils, lymphocytes, leukocytes); decrease in the number of platelets (bruising or bleeding more easily) ✦ reaction related to the infusion of the medicine ✦ decreased secretion of hormones produced by the adrenal glands; overactive thyroid gland; inflammation of the thyroid ✦ decreased sodium, potassium or calcium in the blood ✦ trouble sleeping ✦ dizziness; inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs; lack of energy ✦ dry eye ✦ abnormal heart rhythm ✦ inflammation of the lungs ✦ inflammation of the intestines; inflammation of the pancreas; inflammation of the stomach; dry mouth ✦ inflammation of the liver ✦ red raised rash, sometimes with blisters; inflammation of the skin; dry skin; acne-like skin problem; hair loss ✦ joint pain with swelling ✦ inflammation of the kidneys ✦ flu-like illness; chills ✦ increased levels of amylase, an enzyme that breaks down starch; increased bilirubin in the blood; increased blood levels of a liver enzyme known as alkaline phosphatase; increased calcium in the blood



Uncommon

(may affect up to 1 in 100 people)

KEYTRUDA alone	KEYTRUDA in combination with chemotherapy or chemoradiotherapy	KEYTRUDA in combination with axitinib or lenvatinib
- decreased number of white blood cells (leukocytes); inflammation response against platelets; an increased number of white blood cells (eosinophils) - an immune disorder that can affect the lungs, skin, eyes and/or lymph nodes (sarcoidosis) - decreased secretion of hormones produced by the adrenal glands; inflammation of the pituitary gland situated at the base of the brain; inflammation of the thyroid - type 1 diabetes, including diabetic ketoacidosis - a condition in which the muscles become weak and tire easily; seizure - inflammation of the eyes; eye pain, irritation, itchiness or redness; uncomfortable sensitivity to light; seeing spots - inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis); inflammation of the covering of the heart, which may present as chest pain, shortness of breath or feeling tired (pericarditis); accumulation of fluid around the heart - inflammation of the pancreas; inflammation of the stomach; a sore that develops on the inside lining of your stomach or upper part of your small intestine - thickened, sometimes scaly, skin growth; small skin bumps, lumps or sores; hair colour changes - inflammation of the sheath that surrounds tendons - inflammation of the kidneys - increased level of amylase, an enzyme that breaks down starch	- inflammation response against red blood cells; an increased number of white blood cells (eosinophils) - inflammation of the pituitary gland situated at the base of the brain - type 1 diabetes, including diabetic ketoacidosis - inflammation of the brain, which may present as confusion, fever, memory problems or seizures (encephalitis); seizure - inflammation of the eyes; eye pain, irritation, itchiness or redness; uncomfortable sensitivity to light; seeing spots - inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis); inflammation of the covering of the heart, which may present as chest pain, shortness of breath or feeling tired (pericarditis); accumulation of fluid around the heart - inflammation of the blood vessels - inflammation of the pancreas; a sore that develops on the inside lining of your stomach or upper part of your small intestine - thickened, sometimes scaly, skin growth; patches of skin which have lost colour; small skin bumps, lumps or sores - inflammation of the sheath that surrounds tendons - inflammation of the kidneys; inflammation of the bladder, which may present as frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen - increased level of amylase, an enzyme that breaks down starch	- an increased number of white blood cells (eosinophils) - inflammation of the pituitary gland situated at the base of the brain - type 1 diabetes, including diabetic ketoacidosis - a condition in which the muscles become weak and tire easily; inflammation of the brain, which may present as confusion, fever, memory problems or seizures (encephalitis) - inflammation of the eyes; eye pain, irritation, itchiness or redness; uncomfortable sensitivity to light; seeing spots - inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis); accumulation of fluid around the heart - inflammation of the blood vessels - a sore that develops on the inside lining of your stomach or upper part of your small intestine - dry, itchy skin; thickened, sometimes scaly, skin growth; patches of skin which have lost colour; small skin bumps, lumps or sores; hair colour changes - inflammation of the sheath that surrounds tendons



Rare

(may affect up to 1 in 1,000 people)

KEYTRUDA alone	KEYTRUDA in combination with chemotherapy or chemoradiotherapy	KEYTRUDA in combination with axitinib or lenvatinib
- inflammation response against red blood cells; a condition called haemophagocytic lymphohistiocytosis, where the immune system makes too many infection fighting cells called histiocytes and lymphocytes that may cause various symptoms; feeling weak, lightheaded, short of breath or if your skin looks pale (signs of low level of red blood cells, possibly due to a type of anaemia called pure red cell aplasia) - decreased function of the parathyroid gland, which may present as muscle cramps or spasms, fatigue and weakness (hypoparathyroidism) - a temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome); inflammation of the brain, which may present as 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); swelling of the optic nerve that may result in vision loss in one or both eyes, pain with eye movement, and/or loss of colour vision (optic neuritis); inflammation of the membrane around the spinal cord and brain, which may present as neck stiffness, headache, fever, eye sensitivity to light, nausea or vomiting (meningitis) - inflammation of the blood vessels - lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency); a hole in the small intestines; coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods) - inflammation of the bile ducts - itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area (Stevens-Johnson syndrome or toxic epidermal necrolysis); tender red bumps under the skin - disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome) - inflammation of the bladder, which may present as frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen	- inflammation response against platelets - an immune disorder that can affect the lungs, skin, eyes and/or lymph nodes (sarcoidosis) - decreased function of the parathyroid gland, which may present as muscle cramps or spasms, fatigue and weakness (hypoparathyroidism) - a condition in which the muscles become weak and tire easily; a temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome); swelling of the optic nerve that may result in vision loss in one or both eyes, pain with eye movement, and/or loss of colour vision (optic neuritis); inflammation of the membrane around the spinal cord and brain, which may present as neck stiffness, headache, fever, eye sensitivity to light, nausea or vomiting (meningitis) - lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency) - a hole in the small intestines; coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods) - inflammation of the bile ducts - itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area (Stevens-Johnson syndrome); tender red bumps under the skin; hair colour changes - disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome)	- decreased function of the parathyroid gland, which may present as muscle cramps or spasms, fatigue and weakness (hypoparathyroidism) - swelling of the optic nerve that may result in vision loss in one or both eyes, pain with eye movement, and/or loss of colour vision (optic neuritis) - a hole in the small intestines - itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area (toxic epidermal necrolysis or Stevens-Johnson syndrome) - disease in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren's syndrome) - inflammation of the bladder, which may present as frequent and/or painful urination, urge to pass urine, blood in urine, pain or pressure in lower abdomen   



Unknown

(cannot be estimated from the available data)

KEYTRUDA in combination with axitinib or lenvatinib

⚡ lack or reduction of digestive enzymes made by the pancreas (pancreatic exocrine insufficiency); coeliac disease (characterized by symptoms such as stomach pain, diarrhoea, and bloating after consuming gluten-containing foods)

Rash is more common when KEYTRUDA is given in combination with enfortumab vedotin than when KEYTRUDA is given alone.

The most common side effects when KEYTRUDA is given alone to children are:

- ⚡ fever
- ⚡ decrease in number of red blood cells
- ⚡ vomiting
- ⚡ cough
- ⚡ headache
- ⚡ constipation
- ⚡ stomach pain



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 KEYTRUDA, you should talk to your doctor right away. Be aware that side effects may still occur after receiving the final dose of KEYTRUDA.

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 treatment if your side effects are too severe.

Do not attempt to diagnose or treat side effects yourself.



Don't miss an appointment for treatment with KEYTRUDA

If you stop or interrupt your treatment, it may stop the effect of the medicine. Do not stop your treatment with KEYTRUDA 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. It is important that you receive your medicine as prescribed to get the most out of your treatment. Contact your doctor immediately if you experience any side effects, including those not listed in this brochure.



Remember

KEYTRUDA is a type of therapy that works by helping your immune system fight your cancer that has spread or cannot be taken out by surgery. This type of therapy can sometimes have side effects.

With KEYTRUDA, certain side effects can occur that may be serious.



Contact your doctor as soon as possible if you experience any side effects. This includes any possible side effects not listed in this brochure.

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



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