

Information brochure for patients receiving KEYTRUDA®

Pr **KEYTRUDA**®
(pembrolizumab)



Contains:

- Patient information booklet
- Personal treatment diary
- Wallet card

Read the booklet carefully before you start taking your PrKEYTRUDA® (pembrolizumab) medication and each time you get a refill. The booklet is a summary and will not tell you everything about KEYTRUDA®. Talk to your healthcare team about your medical condition and treatment, and ask if there is any new information about KEYTRUDA®.

What is KEYTRUDA®?

KEYTRUDA®, also known as pembrolizumab, is a prescription medicine used to treat:

- A kind of skin cancer called melanoma in adults
 - KEYTRUDA® may be used alone as your first treatment when your skin cancer:
 - has spread or cannot be removed by surgery (advanced melanoma)
- A kind of lung cancer called non-small cell lung cancer in adults
 - KEYTRUDA® may be used alone as your first treatment when your lung cancer:
 - has spread (advanced lung cancer), or
 - has not spread outside your chest (stage III) and you cannot have surgery or chemotherapy with radiation, and
 - tests positive for “PD-L1”, and
 - if your tumour does not have an abnormal “EGFR” or “ALK” gene

It is not known if KEYTRUDA® is safe and effective in children less than 18 years of age.

People get KEYTRUDA® when their cancer has spread or cannot be taken out by surgery.



How does KEYTRUDA® work?

KEYTRUDA® works by helping your immune system fight your cancer.

You should not use KEYTRUDA® if:

- You have had a severe allergic reaction to pembrolizumab or any other ingredients in KEYTRUDA®

Talk to your healthcare team if you have had any allergic reactions with any medications in the past.

Before you take KEYTRUDA®



Talk to your healthcare team about any health conditions or problems you may have, including if you:

- Have an autoimmune disease (a condition where the body attacks its own cells), such as Crohn's disease, ulcerative colitis or lupus
- Have pneumonia or inflammation of your lungs (called pneumonitis)
- Were previously given ipilimumab, another medicine for treating melanoma, 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 or have had a liver transplant
- Have kidney damage or have had a kidney transplant
- Take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone

There are possible side effects in people who have had an organ transplant.

- 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 you had.
- Complications, including graft-versus-host-disease (GVHD) in people with bone marrow (stem cell) transplant that use donor stem cells (allogeneic). These complications can be severe and can lead to death. They may occur if you had this kind of transplant in the past or if you get it in the future. Your doctor will monitor you for the following signs and symptoms: skin rash, liver inflammation, abdominal pain and diarrhea.

Pregnancy

- If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor.
- KEYTRUDA® can cause harm or death to your unborn baby.
- Females who are able to become pregnant should use an effective method of birth control during therapy and for at least 4 months after the last dose of KEYTRUDA®.

Breast-feeding

- If you are breast-feeding, tell your doctor.
- Do not breast-feed during therapy with KEYTRUDA®.

Tell your healthcare team about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How you are given KEYTRUDA®

- You will receive treatment through an infusion into your vein (intravenous; IV).
- This means that **every 3 weeks** on treatment days, your healthcare provider will place an IV into your vein, and deliver the drug for about 30 minutes.
- Your healthcare team will let you know where your treatment will take place – usually in a hospital outpatient clinic or an infusion clinic.

How long will you stay on therapy?

Every patient is different. Your healthcare team will discuss with you and decide how many treatments you need.

Usual dose

The recommended dose is 200 mg in adults.

If you miss your KEYTRUDA® infusion appointment

- It is very important that you do not miss a dose of this medicine.
- If you miss an infusion, call your healthcare team right away to reschedule your appointment.

If you want more information about KEYTRUDA®:

- Talk to your healthcare team.



Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information at www.merck.ca/static/pdf/KEYTRUDA-PM_E.pdf or by calling Merck Canada Inc. at **1-800-567-2594**.

**Can KEYTRUDA®
cause any
side effects?**



KEYTRUDA® may cause 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. The following side effects have been reported in clinical trials when KEYTRUDA® is given alone:

Very common (may affect more than 1 in 10 people)

- Diarrhea, nausea
- Itching, rash
- Joint pain
- Feeling unusually tired or weak
- Fever
- Feeling less hungry
- Shortness of breath
- Patches of skin that have lost colour (vitiligo)

Common (may affect more than 2 in 100 people and up to 1 in 10 people)

- Flu-like illness
- Dry mouth
- Headache
- Change in your sense of taste
- Cough
- Lack of white blood cells
- Rapid heartbeat
- Cold sores
- Upper respiratory tract infection
- Stuffy nose
- Stomach pain, constipation, vomiting, inflammation of the mucous membrane in the mouth
- Dry skin, redness of the skin, red raised skin rash
- Back pain, muscle aches
- Chills
- Swelling of the face, legs or arms
- Changes in test results:
 - Decrease in the number of red blood cells
 - Decrease in the number of white blood cells
 - Abnormal liver enzyme levels in the blood
 - Decreased sodium levels in the blood
 - Abnormal levels of thyroid stimulating hormone in the blood
 - Increased creatinine levels in the blood
 - Weight loss
 - Weight gain

These are not all the possible side effects you may experience when taking KEYTRUDA®. If you have any side effects, whether or not they are listed here, contact your healthcare team immediately.

Serious side effects and what to do about them

It is important to be aware of serious side effects. If you experience any side effects listed, tell your healthcare team immediately. Your doctor may give you other medicines to prevent more severe complications and reduce your symptoms. Delaying contacting your healthcare team can result in serious side effects that may limit or stop your treatment with KEYTRUDA®.

Be aware of possible side effects

The following pages contain a map of the major symptoms you should look out for.

Note them in your diary immediately if they occur.





Wallet card

This kit includes a wallet card. If you visit the emergency room or a healthcare professional not on your healthcare team, show the wallet card so they will know you are being treated with KEYTRUDA®.

What to look out for



EYES

- My eyesight has changed
- I have noticed a yellowing of my eyes
- I have eye pain



MOUTH AND HEAD

- I have a dry mouth
- I have ulcers in my mouth and/or lining of my nose
- I have noticed a change in my sense of taste
- I feel faint or dizzy
- I have headaches that will not go away or are unusual for me
- I am more thirsty than usual
- I have noticed a swelling of my face
- I am confused
- I have memory problems
- I had a seizure



THROAT AND CHEST

- I have developed a new or worse cough
- I have ulcers in my throat
- My voice is getting deeper
- I feel more short of breath than usual
- I have chest pain
- I have noticed a rapid heartbeat
- I have an irregular heartbeat



SKIN AND HAIR

- I have noticed a yellowing of my skin
- I have noticed that patches of my skin have lost their colour
- I have developed a rash or my skin is itchy
- I have developed blisters and/or sores on my skin
- My skin is peeling
- I have ulcers in my genital area
- I am bleeding or bruising more easily than normal
- I am sweating more than normal
- My hair is falling out
- I have tender lumps on my skin



STOMACH AND BOWELS

- I feel less hungry or more hungry than usual
- I have been nauseous and vomiting
- I am constipated
- I have diarrhea or more bowel movements than usual
- My stools are black, tarry, sticky or have blood or mucus
- I have severe stomach pain or tenderness



URINE

- My urine is dark
- I feel the need to urinate more often
- The colour of my urine has changed
- I have urinary incontinence
- I have difficulty urinating



MUSCLES, JOINTS AND LEGS

- My muscles ache
- I have muscle pain or muscle weakness
- I have severe or persistent muscle or joint pains
- There is swelling in my legs or arms
- I have back pain
- I have pain, numbness or tingling in my arms or legs



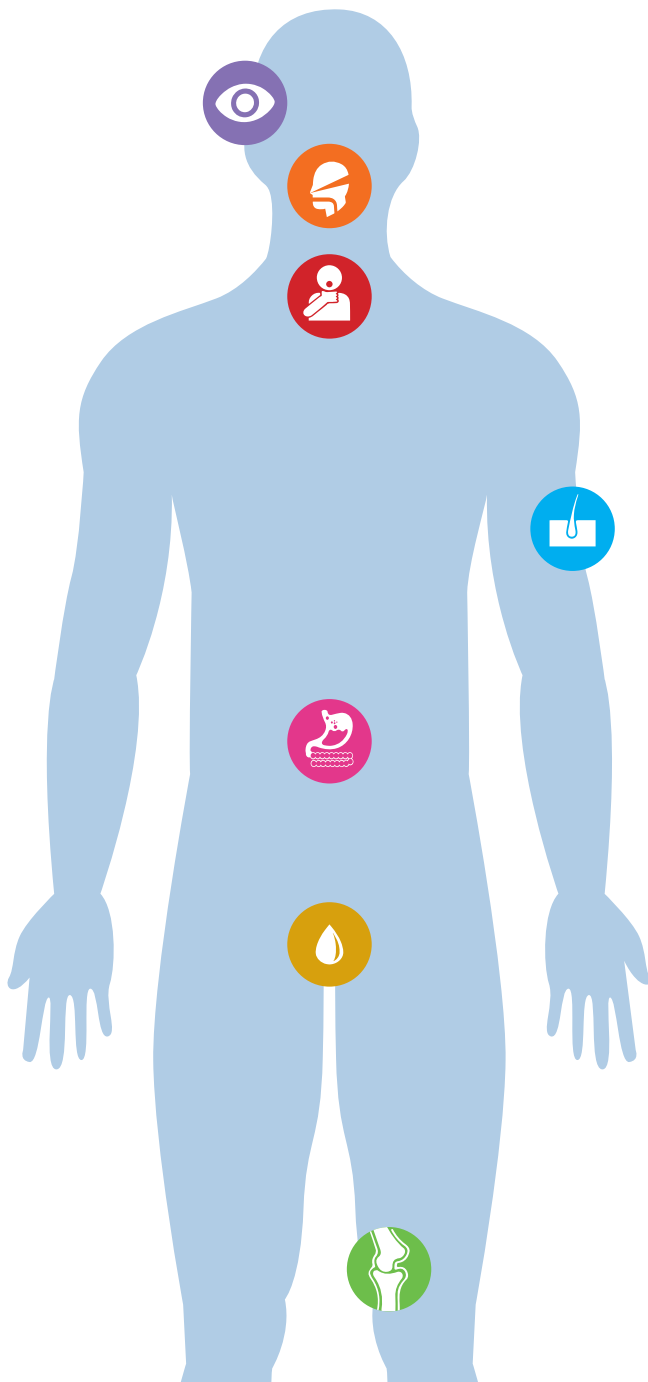
GENERAL

- I feel unusually tired or weak
- I have flu-like symptoms
- I have a fever
- I have chills
- I have lost or gained weight
- I feel colder than normal
- I have swollen lymph nodes



RELATED TO THE INFUSION

- Shortness of breath
- Itching or rash
- Dizziness or fever
- Wheezing
- Flushing
- Feeling like passing out



If you have a symptom or side effect that is not listed here, write it down in your diary included in this package and talk to your healthcare team immediately. Do not wait until your next appointment.

Frequently asked questions



This section answers some of the questions you might have about your treatment. It is a good idea to jot down any other questions you have in your Daily Diary, so that you can ask your healthcare team at your next appointment.

What effect will KEYTRUDA® have on other medications?

It is important to consult your doctor about any medications you are currently taking or planning on taking (including antibiotics, vaccines and over-the-counter medicines).

Can I take vitamins and/or herbal supplements?

You should tell your doctor about all the medicines you take, including vitamins and herbal supplements. Your doctor can help you to decide if they are safe or likely to be helpful.

Can I go on holiday?

Yes. Some extra preparation may be necessary, and we recommended that you keep your treatment details with you while away. It may be useful to take your wallet card with your doctor's contact information

with you. It is important that you do not miss any treatments while away. Discuss with your doctor before you book your holiday.

Can I drink alcohol?

In general, alcohol consumption should be minimized or avoided completely. You can discuss this with your doctor.

Should I use contraception?

Yes. KEYTRUDA® can cause harm to your unborn baby. If you are female and able to become pregnant, you must use effective birth control during therapy and for at least 4 months after the last dose of KEYTRUDA®. Talk to your doctor about birth control methods that you can use during this time, and tell your doctor right away if you become pregnant during treatment.

Can I breast-feed?

You should not breast-feed during your treatment. If before starting treatment you are breast-feeding or plan to breast-feed, be sure to tell your doctor.

Can I drive and/or operate machinery?

You may feel tired while taking KEYTRUDA®, which may affect your ability to drive or use tools or machines. If this happens, avoid these activities.

Can I have my hair dyed?

Some people develop rashes or skin sensitivities while taking this treatment; if you have a rash or sensitive skin on your scalp during treatment, it is possible that hair dye may aggravate this. Check with your doctor if you have any concerns.

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