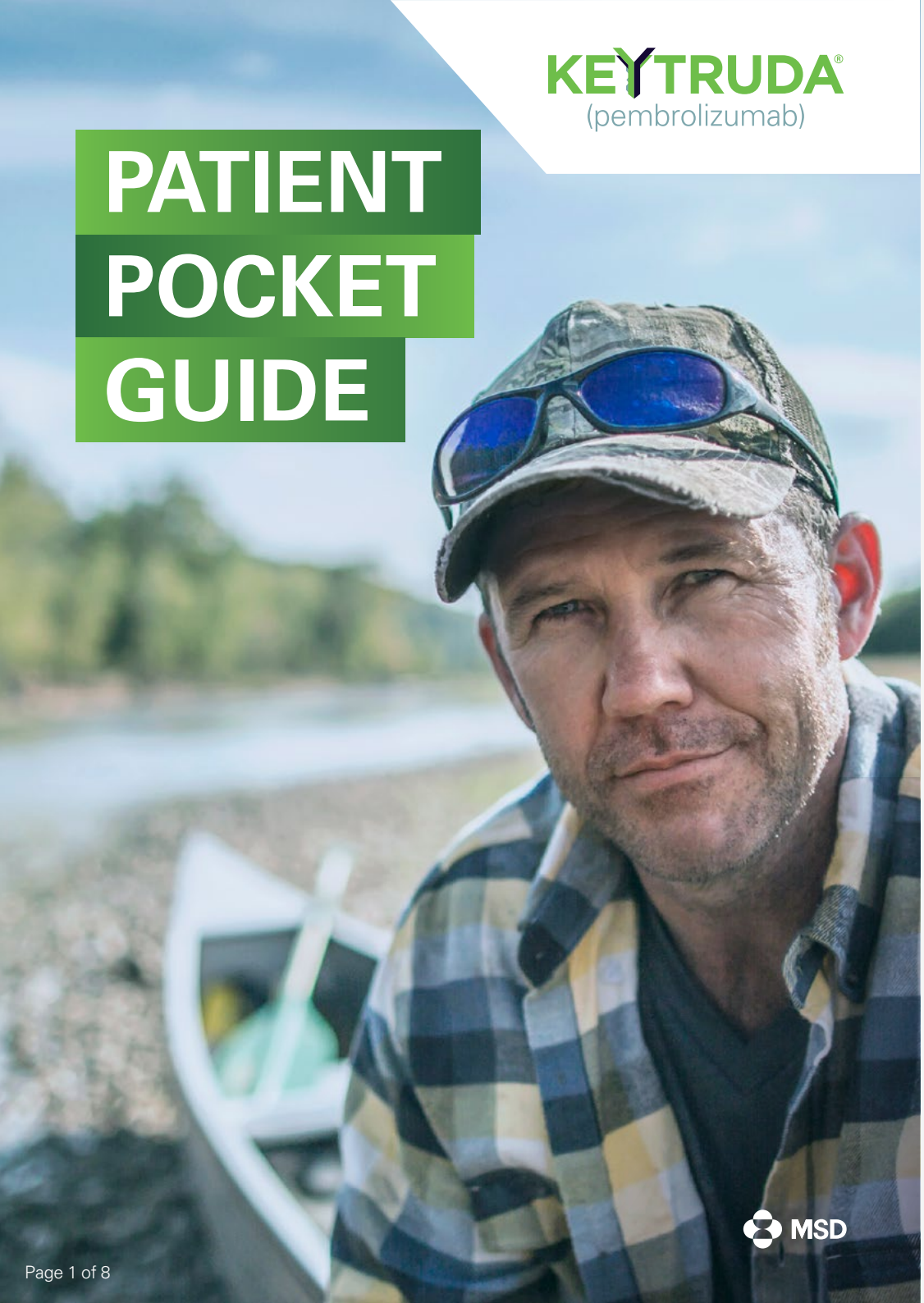
KEYTRUDA®
(pembrolizumab)

PATIENT POCKET GUIDE



MSD

KEYTRUDA® (pembrolizumab) is available as a 100 mg/4 mL concentrate for solution for infusion.

The KEYTRUDA Consumer Medicine Information (CMI) is available at www.medsafe.govt.nz.

KEYTRUDA is a **Prescription Medicine** and may be used in **adults:**

- After surgery to remove melanoma, non-small cell lung cancer or renal cell carcinoma to help prevent the cancer from coming back
- Before surgery to treat triple-negative breast cancer and then continued after surgery to help prevent the cancer from coming back
- To treat bladder cancer which has not spread to nearby tissues but is at high-risk of spreading and where bladder removal is not preferred
- To treat classical Hodgkin Lymphoma (cHL) that has returned or when other treatments have not worked
- To treat certain cancers when the cancer has spread (metastatic) or cannot be removed by surgery (unresectable), such as:
  - melanoma
  - non-small cell lung cancer
  - urothelial carcinoma
  - head and neck squamous cell carcinoma
  - renal cell carcinoma
  - oesophageal carcinoma
  - cutaneous squamous cell carcinoma
  - cervical cancer
  - endometrial carcinoma
  - triple-negative breast cancer
  - a kind of cancer that can occur in any part of the body and is shown by a laboratory test to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
  - colon or rectal cancer that is shown by a laboratory test to be MSI-H or dMMR

KEYTRUDA may be used in **children** with cHL, MSI-H or dMMR cancer, or after surgery to remove melanoma. It is not known if KEYTRUDA is safe and effective in children with MSI-H or dMMR cancer of the brain or spinal cord (central nervous system cancers).

You should not be given KEYTRUDA if you are allergic to pembrolizumab or to any of the other ingredients listed at the end of the CMI.

KEYTRUDA can cause harm or death to unborn babies. Talk to your doctor if you are a woman who could become pregnant and use effective contraception while you are being treated with KEYTRUDA and for at least 4 months after the last dose of KEYTRUDA. Do not breastfeed while taking KEYTRUDA.

Serious immune-mediated side effects have occurred affecting the lungs, intestines, liver, kidneys, hormone glands, blood sugar levels, skin, other organs and in transplant recipients. Some of 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 and you may experience more than one side effect at the same time. Serious infusion reactions have also occurred.

Very common side effects with KEYTRUDA alone include diarrhoea, nausea, itching, rash, joint pain, back pain, feeling tired, cough, patches of discoloured skin, stomach pain, decreased levels of sodium in blood and low levels of thyroid hormone.

When KEYTRUDA was given in combination with *chemotherapy*, hair loss, vomiting, decrease in white-blood cell count, mouth sores, fever, decreased appetite, and swelling of the lining of the digestive system (for example mouth, intestines) were also commonly reported.

When KEYTRUDA was given in combination with *axitinib*, high blood pressure, fatigue, low levels of thyroid hormone, decreased appetite, blisters or rash on palms of your hands and soles of your feet, increase in liver enzyme levels, hoarseness, and constipation were also commonly reported.

When KEYTRUDA was given in combination with *lenvatinib*, high blood pressure, decreased appetite, low levels of thyroid hormone, vomiting, weight loss, headache, constipation, hoarseness, urinary tract infection, stomach-area (abdominal pain), blisters or rash on the palms of your hands and soles of your feet, protein in your urine, increased in liver enzyme levels and feeling weak were also commonly reported.

The most common side effects when KEYTRUDA is given alone to children include fever, vomiting, headache, stomach pain, decrease in number of red blood cells, cough, and constipation. (v48)

KEYTRUDA has risks and benefits. Talk to your doctor to see if KEYTRUDA is right for you. If symptoms continue or you have side effects, tell your doctor.

KEYTRUDA is funded for the treatment of patients with melanoma and non-small cell lung cancer which have spread (metastatic), or is advanced and cannot be removed by surgery – restrictions apply.

KEYTRUDA is not funded for the treatment of all other cancers listed above.

Ask your health professional about the cost of the medicine and any other medical fees that may apply.

Merck Sharp & Dohme (New Zealand) Limited. Level 3, 123 Carlton Gore Road, Newmarket, Auckland.

Please print the KEYTRUDA Patient Pocket Guide and remember to carry it with you at all times.

Tell healthcare professionals, such as other doctors, dentists, and pharmacists that you are being **treated with KEYTRUDA.**

Take this booklet with you if you go to an Emergency Department at a hospital or see any healthcare professional.

MY CONTACT DETAILS

I am being treated with KEYTRUDA.

For healthcare professionals:
If you have any questions about KEYTRUDA, or I present with an adverse event possibly related to KEYTRUDA, please contact my treatment centre immediately.

My details

Name _____

Date KEYTRUDA started _____

Phone _____

MY TREATMENT TEAM

Treatment Centre

Name _____

Phone _____ (work hours)

Phone _____ (after hours)

Oncologist/Specialist

Name _____

Phone _____

Nurse

Name _____

Phone _____

IMPORTANT INFORMATION FOR PATIENTS

KEYTRUDA works with your immune system to help fight your cancer.

KEYTRUDA can also cause your immune system to affect healthy cells in many parts of your body. These side effects can sometimes become serious and in some cases fatal.

DO NOT MANAGE SIDE EFFECTS YOURSELF

If you have any side effect that bothers you or that does not go away, tell your Oncologist/Specialist or Nurse. Side effects may occur during KEYTRUDA treatment and after your last infusion.

YOU MAY BE ABLE TO CONTINUE KEYTRUDA TREATMENT IF SIDE EFFECTS ARE TREATED EARLY

For more information, refer to the KEYTRUDA Consumer Medicine Information by scanning the QR code or via:
www.medsafe.govt.nz/consumers/cmi/k/Keytruda.pdf

IF YOU HAVE ANY OF THE FOLLOWING SIGNS AND SYMPTOMS, CALL OR SEE YOUR ONCOLOGIST/SPECIALIST OR NURSE RIGHT AWAY.

Lung problems

- shortness of breath
- chest pain
- coughing

Problems with your intestines

- diarrhoea or more bowel movements than usual
- your stools are black, tarry, sticky or have blood or mucus
- severe stomach pain or tenderness

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

- rapid heartbeat
- weight loss
- increased sweating
- weight gain
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- muscle aches
- dizziness or fainting
- headaches that will not go away or unusual headache

Liver problems

- nausea or vomiting
- feeling less hungry
- your skin looks yellow
- pain on the right side of your stomach
- the whites of youra eyes look yellow
- dark urine
- you bleed or bruise more easily than normal

Kidney problems

- changes in the amount or colour of your urine

Blood sugar problems

- feeling more hungry or thirsty
- needing to urinate more often
- weight loss

Skin problems

- rash
- itching
- skin blistering, peeling or sores
- ulcers in mouth or in lining of nose, throat, or genital area

Problems in other organs

- muscle pain or weakness
- changes in eyesight
- stomach area pain with nausea and vomiting (pancreatitis)
- shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis)
- confusion, fever, memory problems, or seizures (encephalitis)
- swollen lymph nodes, rash or tender lumps on skin, cough, or eye pain (sarcoidosis)
- 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 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 (haemolytic anaemia)
- pain in the upper right part of the stomach, swelling of the liver or spleen, fatigue, itching or yellowing of the skin or whites of eyes (sclerosing cholangitis)
- decreased ability of the pancreas to make digestive enzymes, which may include diarrhoea with loose and oily stools, weight loss, metabolic bone disease, and vitamin or mineral deficiencies (exocrine pancreatic insufficiency)

Infusion (IV) reactions

- shortness of breath
- itching or rash
- dizziness
- fever

IMPORTANT INFORMATION FOR HEALTHCARE PROFESSIONALS

KEYTRUDA is an immunotherapy and is used to treat certain types of cancer.

Immune-mediated adverse reactions, including severe and fatal cases, have occurred in patients receiving KEYTRUDA. In clinical trials, most immune-mediated adverse reactions occurred during treatment, were reversible and managed with interruptions of KEYTRUDA, administration of corticosteroids and/or supportive care.

Immune-related adverse reactions have also occurred after the last dose of KEYTRUDA. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.

MANAGING SUSPECTED IMMUNE-MEDIATED ADVERSE REACTIONS

Contact the patient's treatment centre for advice.

For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm aetiology or exclude other causes. Assess patients for immune-mediated adverse reactions, particularly colitis, pneumonitis, hepatitis, nephritis, endocrinopathies, severe skin reactions, transplant-related adverse reactions and infusion-related reactions.

Based on the severity of the adverse reaction, withhold KEYTRUDA and consider administration of corticosteroids as recommended in the Data Sheet.

For more information, refer to the KEYTRUDA Data Sheet available by scanning the QR code or via the URL on the following page.

PATIENTS

For more information, refer to the KEYTRUDA Consumer Medicine Information by scanning the QR code or via:
www.medsafe.govt.nz/consumers/cmi/k/Keytruda.pdf

HEALTHCARE PROFESSIONALS

For more information, refer to the KEYTRUDA Data Sheet by scanning the QR code or via:
www.medsafe.govt.nz/Profs/DataSheet/k/Keytruda.pdf

References:

KEYTRUDA Consumer Medicine Information.
KEYTRUDA Data Sheet.

NZ-KEY-00858. TAPS NP19803. TAPS DA 2339KN.
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