This medicine is subject to additional monitoring due to provisional approval of an extension of indication. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

This medicine has provisional registration in Australia for the treatment of adult patients with locally advanced or recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation, for the treatment of patients with high-risk, non-muscle invasive bladder cancer that has not responded to treatment with Bacillus Calmette-Guerin (BCG), and the treatment of adult and paediatric patients with unresectable or metastatic tumour mutational burden-high (TMB-H) solid tumours. The decision to provisionally register these new uses of the medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for these uses

Important information for healthcare professionals

This patient is being treated with KEYTRUDA which can cause immune-mediated adverse reactions that may appear any time during treatment or even after treatment. Assess patients for signs and symptoms of immune-mediated adverse reactions. Early diagnosis and appropriate management are essential to minimise any consequences of immune-mediated adverse reactions.

For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm aetiology or exclude other causes. Based on the severity of the adverse reaction, withhold KEYTRUDA and consider administration of corticosteroids. Specific guidelines for managing immune-mediated adverse reactions are available in the Product Information for KEYTRUDA

Consultation with an oncologist or other medical specialist may be helpful for the management of organ-specific immune-mediated adverse reactions.

Please consult the Product Information for KEYTRUDA at www.msdinfo.com.au/keytrudapi or call MSD Medical Information at 1800 818 553 for more information.

Contact details

This patient is being treated with KEYTRUDA (pembrolizumab).

If you have any questions, or if the patient presents with an adverse event possibly related to KEYTRUDA, please contact the treatment centre immediately.

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Treatment centre

Treating oncologist/haematologist

Phone

Phone (after hours)



References:

KEYTRUDA Product Information, http://msdinfo.com.au/keytrudapi

KEYTRUDA Consumer Medicine Information, http://msdinfo.com.au/keytrudacmi.

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KEYTRUDA

(pembrolizumab)

Patient wallet card

For more information, speak to your treating care team, or refer to the Consumer Medicine Information for KEYTRUDA, which is available at www.msdinfo.com.au/keytrudacmi.

Important information for patients prescribed KEYTRUDA

KEYTRUDA may cause some serious side effects which can sometimes become life-threatening and lead to death. These may happen any time during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

Contact your treating care team right away if you develop any side effects, or if they get worse.

Early treatment of side effects may stop them becoming more serious.



This card does not take the place of speaking to your treating care team. They are there to help you – don't hesitate to contact them anytime.

- Do not attempt to diagnose or treat side effects yourself.
- Do not stop your treatment with KEYTRUDA unless you have discussed this with your doctor.
- Take this card with you at all times, especially when you travel, whenever you go to the emergency room, or when you must see another doctor.
- Be sure to notify any healthcare professional you see that you are being treated with KEYTRUDA and show them this card.



Scan the QR Code for a digital version of this wallet card to store on your phone.

Side effects

Call or see your treating care team right away, or go straight to the Emergency Department at your nearest hospital if you notice any of the below side effects.

Lungs

- Shortness of breath
- Chest pain
- Coughing

Kidney

• Changes in the amount or colour of your urine

Intestines

- Diarrhoea or more bowel movements than usual
- Stools that are black, tarry, sticky or have blood or mucus
- Severe stomach pain or tenderness

Blood sugar problems

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

Liver

- Nausea or vomiting
- Feeling less hungry
- Pain on the right side of your stomach
- Your skin looks yellow
- The whites of your eyes look yellow
- Dark urine
- You bleed or bruise more easily than normal

Hormone glands (e.g. thyroid, pituitary and adrenal glands)

- Rapid heart beat
- Weight loss or gain
- Increased sweating
- Hair lossFeeling cold
- Constipation
- Your voice gets deeper
- Muscle aches
- Dizziness or fainting
- Headaches that will not go away or
- Headaches that w unusual headache

KEYTRUDA may cause other side effects that are not listed here. Please refer to the KEYTRUDA Consumer Medicine Information for information on the other serious side effects to watch out for.