

NGĀ MŌHIOHIO MĀ KOUTOU KO TŌ WHĀNAU



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
 - gastric or gastroesophageal junction (GEJ) adenocarcinoma
 - 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, decreased white-blood cell count, mouth sores, fever, decreased appetite, decreased number of red blood cells, decreased number of platelets in the blood 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, increase 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. (v50)

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 to treat certain patients with the following types of advanced cancers: melanoma, non-small cell lung cancer, MSI-H or dMMR colorectal cancer, triple-negative breast cancer, head and neck squamous cell carcinoma, urothelial carcinoma, and classical Hodgkin lymphoma - further 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.

NGĀ MŌHIOHIO MŌ KEYTRUDA MĀ KOUTOU KO TŌ WHĀNAU



Ki te hiahia koe ki ētahi mōhiohio anō, me kōrero koe ki tō Rata Mate Pukupuku, ki tō Nēhi Mate Pukupuku rānei, me titiro rānei ki ngā Mōhiohio Rongoā mā te Kiritaki mō KEYTRUDA.

He aha a KEYTRUDA?

Ka tukuna a KEYTRUDA i runga i te whakahau rongoā, arā, e kīia ana he rongoa tūtohu. Kei roto i KEYTRUDA ko te matū hohe, ko pembrolizumab.

E kīia ana a KEYTRUDA he haumanu awhikiri i te mea ka mahi tahi me te pūnaha awhikiri o te tinana ki te tautoko i tā te pūnaha awhikiri kimi i ngā pūtau mate pukupuku, me te whawhai i aua pūtau. Ka āwhina a KEYTRUDA i te pūnaha awhikiri ki te mahi i tāna mahi - arā, ki te āwhina i tōu ake tinana ki te whawhai ki te mate pukupuku.

Ehara a KEYTRUDA i te hahau.

Ka pēhea te tukuna o KEYTRUDA

Ka whāngaia te KEYTRUDA rā roto i tētahi ngira ki tētahi ia-auraki, i roto i te 30 meneti. I te nuinga o te wā, tukuna ai a KEYTRUDA i ia 3 wiki, i ia 6 wiki rānei, i runga anō i te āhua o te pota ka tukuna ki a koe, e kīia ana ko 'ngā hurihanga'.

Ka tukuna pea a KEYTRUDA i te taha o ētahi atu rongoā awhikiri pukupuku. He mea nui kia pānuitia hoki e koe ngā Mōhiohio Rongoā mā te Kiritaki mō ērā atu rongoā. Mēnā he pātai āu mō aua rongoā, me pātai atu ki tō rata.

I te nuinga o te wā, ka tukuna ō maimoatanga e te Rata/Mātanga Mate Pukupuku, e te Nēhi rānei i tētahi hōhipera. Mā tō Rata/Mātanga Mate Pukupuku e whakatau te nama o ngā maimoatanga/huringa hei whiwhi māu.



Whāngaia ā-iaia



I roto i te 30 meneti



I ia 3 wiki, i ia 6 wiki rānei,
i runga anō i te āhua o te pota
ka tukuna ki a koe

Ngā āhuatanga hei whakaaroaro i mua i te maimoatanga

Koe e kore e tika kia hoatu KEYTRUDA mena he mate mate koe ki te pembrolizumab, ki tetahi atu mea whakauru rānei kua whakarārangitia i te mutunga o te KEYTRUDA Rongoā korero rongoa mo nga kaihoko.

Mēnā kei te hapū koe, ki ō whakaaro rānei kei te hapū pea koe, kei te hiahia rānei koe kia hapū koe, me kōrero atu ki tō rata. Ka tūkinu pea, ka whakamate pea rānei a KEYTRUDA i tō pēpi kāore anō kia whānau mai. Mēnā he wahine koe ka taea e koe te hapū, me mātua whakamahi koe i te ārai hapūtanga whaitake i a koe e whakamaimoatia ana ki a KEYTRUDA, ka mutu, me whakamahi tonu mō te 4 marama, mō tētahi wā roa ake rānei, ā muri i te pota KEYTRUDA whakamutunga. Mēnā kei te whāngai ū koe, me kōrero atu ki tō rata. Kua e whāngai ū i te wā e whakamaimoatia ana koe ki a KEYTRUDA.

Ka pā atu pea ētahi pānga kino i a koe e whiwhi ana i a KEYTRUDA

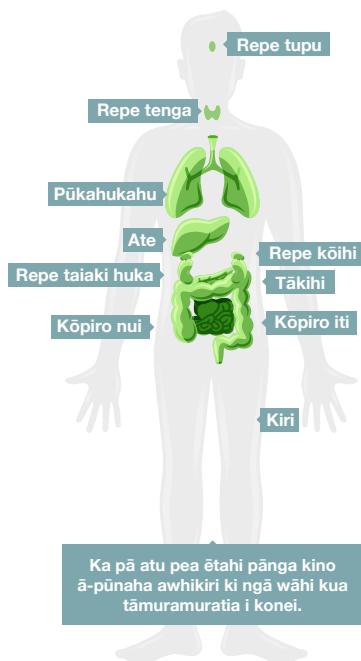
I a koe e whakamaimoatia ana ki a KEYTRUDA, ka auau ngā whakaritenga hei aroturuki i tō hauora me ngā pānga kino, mēnā rā he pānga kino.

Pērā i ngā rongoā katoa, ka ahu atu pea i a KEYTRUDA ētahi pānga kino, engari kāore e pā atu aua pānga kino ki ngā tāngata katoa.

Ka kōrero tō rata ki a koe mō aua pānga kino, ā, ka whakamārama i ngā tūraru me ngā painga o tō maimoatanga.

Nā KEYTRUDA ka pāngia pea e te pūnaha awhikiri ngā pūtau hauora i ētahi atu wāhanga o tō tinana. I ētahi wā he taumaha tonu ēnei pānga kino, ka mutu, i ētahi wā, he pānga whakamate.

He mea nui kia wawe tonu te whakamaimoa i a koe, mēnā ka pāngia koe e ngā pānga kino.



Me kōrero atu ki tō Rata/Mātanga Mate Pukupuku mēnā ka kite koe i ētahi pānga kino, i ētahi tohumate rānei. Mā te whakamaimoa wawe, ka aukatia pea te taumaha haere o ngā pānga kino.

Ka taea pea e koe te maimoatanga KEYTRUDA te whiwhi tonu, ahakoa ngā pānga kino, mēnā ka wawe te whakamaimoa i a koe.

Engari, ki te taumaha haere ngā pānga kino, ka whakamutua pea tō whakamaimoatia ki a KEYTRUDA. Kua koe e ngana ki te patu takitahi i ngā pānga kino.

Ngā pānga kino e rite tonu ana te kitea

Kua kitea ēnei pānga kino i roto i ngā whakamātautau haumanu.

Ko ngā pānga kino a KEYTRUDA e tino kitea ana (arā, neke atu i te 1 i te 10 ngā tāngata ka pāngia pea) ko ēnei:

- Ka ngaro te tae o ētahi wāhanga o te kiri
- Te mamae o te puku
- Ka heke ngā rahinga konutai i roto i te toto
- Ka iti te taiaki repe tenga
- Te mate tikotiko, te whakapairuaki
- Te mamae pona
- Te mamae tuarā
- Te mangeo, te kōpukupuku
- Te ngenge
- Te maremare

Ngā pānga kino ā-pūnaha awhikiri

I te mea ka mahi tahi a KEYTRUDA me te pūnaha awhikiri, he pānga kino ka ahu atu pea i ngā pānga a te KEYTRUDA ki te pūnaha awhikiri.

He mea nui kia mataara ki ēnei pānga kino ki te pūnaha awhikiri kia wawe ai te maimoatanga. Mā konei e taea pea e koe te maimoatanga KEYTRUDA te whiwhi tonu.

Mēnā ka taea ō pānga kino te āta whakahaere, ka taea pea e koe te maimoatanga KEYTRUDA te whiwhi tonu.



Ina whiwhi koe i a KEYTRUDA, ka pā atu pea ki a koe ētahi pānga kino taumaha. I ētahi wā, he mate taihemo pea, ka mutu, ko te mate pea te otinga atu. Ka pā atu ēnei pānga kino i te wā o tō maimoatanga, ā muri rānei i te mutunga o tō maimoatanga. Neke atu pea i te kotahi ngā pānga kino ka pā atu ki a koe i te wā kotahi.

Me wawe tonu tō waea atu, tō haere atu rānei ki tō Rata, ki tō Nēhi rānei, mēnā ka pā atu ki a koe ētahi o ēnei tohu, o ēnei tohumate rānei:

Ngā tohu me ngā tohumate o ngā raru pūkakahuka

- ka hēmanawa
- te mamae o te uma
- te maremare

Ngā tohu me ngā tohumate o ngā raruraru o ō kōpiro

- te mate tikotiko, ka auau ake rānei te haere ki te tiko
- he pango ō hamuti, he tā te āhua, he piripiri, he toto kei roto, he kea rānei kei roto
- he tino nui te mamae o te puku (arā, te whēkau e kīia nei te “stomach”), he pāwera rānei te puku

Ngā tohu me ngā tohumate o ngā raru o ngā repe taiaki (inā rā te repe tenga, te repe tupu, me te repe kōihi)

- ka tere te kapa manawa
- ka heke tō taumaha
- ka nui ake te werawera
- ka taumaha haere koe
- ka kore haere ngā makawe
- ka rongo i te mātao
- ka kōroke
- ka hahaka iho tō reo
- ka mamae ngā uaua
- ka pōātinitini, ka tirehe rānei
- he ānini mau roa o te mähunga, he ānini mähunga whanokē rānei

Ngā tohu me ngā tohumate o ngā raru huka toto

- ka nui ake te hiakai, te hiainu rānei
- ka nui ake te hiamimi
- ka heke te taumaha

Ngā tohu me ngā tohumate o ngā raru tākihi

- kua rerekē te nui, te tae rānei o tō mimi

Ngā tohu me ngā tohumate o ngā raru o te kiri

- te kōpukupuku
- te mango
- he pūputa kiri, he horehore, he hakahaki rānei
- he mariaio i rō waha, i rō ihu, i rō korokoro, i ngā taihemahema rānei

Ngā tohu me ngā tohumate o ngā raru ate

- te whakapairuaki, te ruaki rānei
- ka iti iho te hiakai
- ka mamae te taha matau o tō puku
- ka kōwhai te āhua o tō kiri
- ka kōwhai te āhua o ngā wāhi mā o ō karu
- ka uriuri te mimi
- ka māmā ake te toto, te marū rānei

Ngā tohu me ngā tohumate o ngā tauhohenga whāngai iaia (IV)

- ka hēmanawa
- te mango, te kōpukupuku
- te pōātinitini
- te kirikā

Ngā tohu me ngā tohumate o ngā raruraru i ētahi atu whēkau

- te mamae uaua, te ngoikore rānei
- ka rerekē tāu kite
- te mamae o te puku me te whakapairuaki me te ruaki (pancreatitis)
- te pōrauraha, te kirikā, ngā raruraru maumahara, te hukihuki (encephalitis)
- ka pupuhi ngā pona taikiri, he kōpukupuku te kiri, he pōrukuru pāwera rānei i te kiri, ka maremare, ka mamae rānei ngā karu (sarcoidosis)
- te hēmanawa, te manawa whakahipahipa, te ngenge, te mamae uma rānei (myocarditis)
- te mamae, te tengatenga, te kēkerewai, te ngoikore rānei i ngā ringaringa me ngā waewae; ngā raruraru tōngāmimi, ngā raruraru kōpiro rānei, tae atu ki te pikinga o te auau o te hiamimi, te mate mimi tututuru, te uaua o te mimi me te kōroke (myelitis)
- te kakātanga o ngā ia toto (vasculitis)
- ka heke te kaha o te repe parathyroid, me te aha, ka pā atu pea te kuiki uaua, te hukihuki rānei, te ngenge me te ngoikore (hypoparathyroidism)
- te mumura o te rākau o te kopu, tērā pea ko te mamae kopu, te whakangāwari rānei, te paipairuaki, te ruaki rānei (gastritis)
- ko te whakangaromanga o ngā pūtau toto whero, tērā pea ko te mimi pōuri, te kiri, te kiri kōwhai rānei/kanohi, te māmā, te rongo i te ngenge, te tere ngakau, te poto rānei o te manawa (haemolytic anaemia)
- ka mamae te taha matau o runga o te puku, ka pupuhi te ate, te kōateate rānei, ka ngenge, ka mangeo, ka kōwhai te kiri, ka kōwhai rānei te wāhi mā o ngā karu (sclerosing cholangitis)
- he iti iho te kaha o te pancreas ki te hanga i ngā whākōki kūnatu, tērā pea ko te diarrhoea me ngā stools tārewa, hinu hoki, te ngaronga taumaha, te mate o te wheua metabolic, me te vitamine, ngā hēnga kohuke rānei (exocrine pancreatic insufficiency)

Ka pā atu pea ngā pānga kino o te maimoatanga KEYTRUDA ki te tangata kua whiwhi i tētahi huaranga whēkau

- Te ākiri i te whēkau i huarangatia. Ka nui ake pea te tūraru ākiri huaranga whēkau i te hunga kua whiwhi i ngā huaranga whēkau. Me kōrero tō rata ki a koe mō ngā tohu me ngā tohumate e tika ana kia pūrongorongotia e koe, ā, me āta aroturuki tō rata i a koe, i runga anō i te momo huaranga i whiwhi ai koe.
- Mate huaranga-tohe-i-te-papa (GVHD) i roto i te hunga kua whiwhi i ngā huaranga mongamonga kōiwi (pūtau tātā) whai pūtau tātā kaituku (allogeneic). Ka pā atu pea te GVHD mēnā kua whiwhi koe i tēnei huaranga. Ka aroturuki tō rata i a koe kei puta ēnei tohu me ēnei tohumate: te kōpukupuku kiri, te kakātanga o te ate, te mamae o te puku, me te mate tikotiko.

Ki te hiahia koe ki ētahi atu mōhiohio, me kōrero koe ki tō Rata Mate Pukupuku, ki tō Nēhi Mate Pukupuku rānei, me titiro rānei koe ki ngā Mōhiohio Rongoā mā te Kiritaki mō KEYTRUDA.

Tohutoro: ngā Mōhiohio Rongoā mā te Kiritaki mō KEYTRUDA - <https://www.medsafe.govt.nz/consumers/cmi/k/Keytruda.pdf>

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NZ-KEY-00844v9.0. TAPS NP19286. TAPS DA 2419KN.
Issued October 2024. MSD13410.

