KEYTRUDA first-line treatment options for advanced or metastatic NSCLC[1]

KEYTRUDA® (pembrolizumab)

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

Please review the KEYTRUDA Data Sheet before prescribing. The Data Sheet is available at www.medsafe.govt.nz.

INDICATIONS: In combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic non-squamous non-small cell lung carcinoma (NSCLC), with no EGFR or ALK genomic tumour aberrations. In combination with carboplatin and either paclitaxel or nab-paclitaxel for first-line treatment of metastatic squamous NSCLC. As monotherapy for first-line treatment of patients with NSCLC whose tumours express PD-L1 [tumour proportion score (TPS) ≥1%] as determined by a validated test, with no EGFR or ALK genomic tumour aberrations and are either; metastatic, or stage III where patients are not candidates for surgical resection or definitive chemoradiation. As monotherapy for the treatment of patients with advanced NSCLC with a PD-L1 TPS level ≥1% as determined by a validated test and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumour aberrations should have received prior therapy for these aberrations prior to receiving KEYTRUDA. As monotherapy for the adjuvant treatment of patients with Stage IB (T2a ≥4 cm), II, or IIIA NSCLC who have undergone complete resection. See Data Sheet for other indications.

CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the Data Sheet. See Data Sheet for further information.

PRECAUTIONS: Severe and fatal cases of immune-mediated adverse reactions have occurred. Immune-related adverse reactions have occurred after discontinuation of treatment with KEYTRUDA and can affect more than one body system simultaneously. For management of immune-mediated adverse reactions, see Data Sheet. Immune-mediated adverse reactions have occurred as follows: pneumonitis (including fatal cases), colitis, hepatitis, nephritis, adrenal insufficiency, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis, severe skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis [including fatal cases], bullous pemphigoid), uveitis, myositis, Guillain-Barre syndrome, pancreatitis, encephalitis, sarcoidosis, myasthenic syndrome/myasthenia gravis (including exacerbation), myelitis, vasculitis, hypoparathyroidism, gastritis, haemolytic anaemia, pericarditis, myocarditis, sclerosing cholangitis, exocrine pancreatic insufficiency, solid organ transplant rejection, acute graft-versus-host-disease (GVHD) including fatal GVHD with a history of allogeneic hematopoietic stem cell transplantation, higher than expected frequencies of Grades 3 and 4 ALT and AST elevations in advanced RCC when used in combination with axitinib, increased mortality when in combination with dexamethasone and a thalidomide analogue in multiple myeloma (not indicated), severe infusion reactions including hypersensitivity and anaphylaxis. Monitor thyroid and liver function. Limited data in patients with active infections and with history of severe adverse reaction to ipilimumab – use caution. No data in severe renal impairment, or moderate or severe hepatic impairment. Pregnancy (Category D). See Data Sheet for further information.

INTERACTIONS: None expected. Avoid systemic corticosteroids or immunosuppressants prior to treatment (except as premedication in combination with chemotherapy).

ADVERSE EVENTS: Monotherapy: pneumonitis, colitis, diarrhoea, pyrexia, fatigue, pruritus, rash, nausea, hypothyroidism, hyperthyroidism, adrenal insufficiency, hepatitis, hypophysitis, nephritis, type 1 diabetes mellitus, arthralgia, cough, back pain, vitiligo, lymphopenia, hypertriglyceridemia, abdominal pain, hyponatremia, hyperglycaemia, hypoalbuminemia, increased AST and ALP, anaemia, dyspnoea, constipation, increased lipase; Combination (where not already listed under Monotherapy) *with chemotherapy:* alopecia, asthenia, decreased neutrophil count, neutropenia, thrombocytopenia, mucosal inflammation, stomatitis, vomiting, decreased white blood cell count, decreased appetite, decreased platelet count. See Data Sheet for further information.

DOSAGE AND ADMINISTRATION: Adults: 200 mg every 3 weeks or 400 mg every 6 weeks. Paediatrics (see Indications): 2 mg/kg (up to 200 mg) every 3 weeks. Administered as an intravenous infusion over 30 minutes. For use in combination, please review the Data Sheets for KEYTRUDA and the relevant concomitant therapies. KEYTRUDA should be administered first when given in combination with intravenous chemotherapy. Treat with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e. an initial transient increase in tumour size or small new lesions followed by shrinkage) have been observed. Clinically stable patients (i.e. asymptomatic and not requiring urgent intervention) with initial evidence of progression can remain on treatment until confirmed. For the adjuvant treatment of NSCLC, treat with KEYTRUDA for up to one year or until disease recurrence or unacceptable toxicity. See Data Sheet for further information. (v54.02)

KEYTRUDA is funded for the first-line treatment of patients with advanced or metastatic NSCLC. Further restrictions apply, see pharmac.govt.nz.[2]

KEYTRUDA is unfunded for the other NSCLC indications – a charge will apply.

References: 1. KEYTRUDA Data Sheet. **2.** PHARMAC. Pharmaceutical Schedule. Available at: https://pharmac.govt.nz/pharmaceutical-schedule Accessed 30 October 2024.

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KEYTRUDA® (pembrolizumab)

Patients with Metastatic NSCLC*

NON-EXPRESSORS (PD-L1 TPS <1%)

+ **Non-Squamous** with no EGFR/ALK genomic tumour aberrations → **KEYTRUDA + platinum + pemetrexed** KEYNOTE-189[1]

+ **Squamous** → **KEYTRUDA + carboplatin + paclitaxel/ nab-paclitaxel** KEYNOTE-407[1]

EXPRESSORS (PD-L1 TPS ≥1%)

+ **Non-Squamous** with no EGFR/ALK genomic tumour aberrations → **KEYTRUDA + platinum + pemetrexed** KEYNOTE-189[1]

+ **Squamous** → **KEYTRUDA + carboplatin + paclitaxel/ nab-paclitaxel** KEYNOTE-407[1]

COMBINATION THERAPY
KEYTRUDA + chemotherapy as first-line treatment for your appropriate patients, **regardless of PD-L1 expression**[1]

OR

Advanced or Metastatic NSCLC

KEYTRUDA MONOTHERAPY
KEYNOTE-024^[1] and KEYNOTE-042#*[1]

^Patients in KEYNOTE-024 had tumours that expressed PD-L1 with a TPS ≥50%.
#Patients in KEYNOTE-042 had tumours that expressed PD-L1 with a TPS ≥1%.

MONOTHERAPY
KEYTRUDA as first-line monotherapy where tumours **express PD-L1 (TPS ≥1%)** and no EGFR/ALK genomic tumour aberrations[1]

*KEYNOTE-042 also included Stage III where patients were not candidates for surgical resection or definitive chemoradiation.[1]

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