KEYTRUDA®
(pembrolizumab) for Injection 50 mg

SYMPTOM CHECKLIST (FOR IMMUNE-RELATED ADVERSE REACTIONS)[1]

- KEYTRUDA adverse events can occur at any time during or after treatment
- The following signs and symptoms may indicate immune-related adverse events from treatment

Patient Name: _____ Date: _____

Ask your patients if they have felt or noticed any changes in the following:

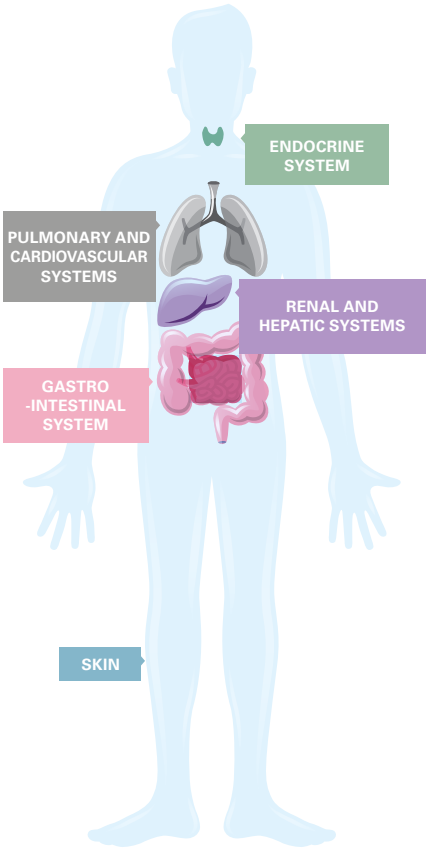
ENDOCRINE SYSTEM			Please provide any details
Appetite changes?	☐ NO	☐ YES	
Weight changes?	☐ NO	☐ YES	
Drowsy, weak or extremely tired?	☐ NO	☐ YES	
Cold?	☐ NO	☐ YES	
Sweaty?	☐ NO	☐ YES	
Headaches?	☐ NO	☐ YES	
Dizziness or lightheaded?	☐ NO	☐ YES	
Changes in mood (e.g. irritability)?	☐ NO	☐ YES	
Rapid heartbeat?	☐ NO	☐ YES	
Flu-like symptoms?	☐ NO	☐ YES	
Muscles aches?	☐ NO	☐ YES	

PULMONARY AND CARDIOVASCULAR SYSTEMS			Please provide any details
Coughing (either new or worsening)?	☐ NO	☐ YES	
Chest pain?	☐ NO	☐ YES	
Shortness of breath?	☐ NO	☐ YES	

SKIN			Please provide any details
Rash?	☐ NO	☐ YES	
Itches?	☐ NO	☐ YES	
Pigmentation or colour changes?	☐ NO	☐ YES	
Any other skin changes?	☐ NO	☐ YES	

GASTRO-INTESTINAL SYSTEMS			Please provide any details
Altered bowel habits (diarrhoea, constipation)?	☐ NO	☐ YES	# of movements/day:
Change in stool appearance (black, tar-like, blood, mucus-like)?	☐ NO	☐ YES	
Nausea?	☐ NO	☐ YES	
Vomiting?	☐ NO	☐ YES	
Stomach pains (e.g. tender or cramping)?	☐ NO	☐ YES	

RENAL AND HEPATIC SYSTEMS			Please provide any details
Change in urine quantity?	☐ NO	☐ YES	
Change in urine colour?	☐ NO	☐ YES	
Yellowing of skin and/or eyes?	☐ NO	☐ YES	
Swelling of ankles?	☐ NO	☐ YES	
Other bleeding, bruising or swelling?	☐ NO	☐ YES	
AST/ALT 1–3 x ULN or higher?	☐ NO	☐ YES	



Note to Healthcare Professionals: Any organ can be affected. This checklist is not intended to replace clinical judgement. Please review the KEYTRUDA Data Sheet for further information. Should you wish to report a product complaint (including any adverse events), please email dpoc.australia@merck.com.

	Grade 1	Grade 2	Grade 3	Grade 4
Pneumonitis[2]	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; medical intervention indicated; limiting instrumental activities of daily living	Severe symptoms; limiting self care ADL; oxygen indicated	Life-threatening respiratory compromise; urgent intervention indicated (e.g. tracheotomy or intubation)
Pruritis or Rash[2]	Mild or localised; topical intervention indicated	Intense or widespread; intermittent; skin changes from scratching (e.g. edema, papulation, excoriations, lichenification, oozing/crusts); oral intervention indicated; limiting instrumental activities of daily living	Intense or widespread; constant; limiting self care activities of daily living or sleep; oral corticosteroid or immunosuppressive therapy indicated	
Colitis[2]	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Abdominal pain; mucus or blood in stool	Severe abdominal pain; change in bowel habits; medical intervention indicated; peritoneal signs	Urgent intervention indicated
Myocarditis[2]	Asymptomatic with laboratory (e.g. BNP [B-Natriuretic Peptide]) or cardiac imaging abnormalities	Symptoms with mild to moderate activity or exertion	Severe with symptoms at rest or minimal activity or exertion; intervention indicated	Life-threatening consequences; urgent intervention indicated (e.g. continuous IV therapy or mechanical hemodynamic support
Hepatitis[2]	AST/ALT 1–3 x ULN or Total bilirubin 1–1.5 x ULN	AST/ALT >3 TO 5 x ULN or Total bilirubin >1.5 to 3 ULN	AST/ALT >5 x ULN or Total bilirubin >3 x ULN	
Nephritis[2]	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily living	Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of hospitalisation indicated; disabling; limiting self care activities of daily living	Urgent intervention indicated
Hypophysitis[2]	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated	Minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily living	Severe or medically significant but not immediately life-threatening; hospitalisation or prolongation of hospitalisation indicated; disabling; limiting self care activities of daily living	Urgent intervention indicated
Hyperthyroidism[2]	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; thyroid suppression therapy indicated; limiting instrumental activities of daily living	Severe symptoms; limiting self care activities of daily living; hospitalisation indicated	Urgent intervention indicated
Hypothyroidism[2]	Asymptomatic; clinical or diagnostic observations only; intervention not indicated	Symptomatic; thyroid replacement indicated; limiting instrumental activities of daily living	Severe symptoms; limiting self care activities of daily living; hospitalisation indicated	Urgent intervention indicated

Continue treatment and monitor. Manage with supportive care

Withhold KEYTRUDA and administer corticosteroids

Permanently discontinue KEYTRUDA and administer corticosteroids

References: 1. KEYTRUDA Data Sheet. 2. Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0. Published: May 28, 2009 (v4.03: June 14, 2010), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES National Institutes of Health National Cancer Institute

KEYTRUDA (pembrolizumab) 50mg powder for infusion. Before prescribing KEYTRUDA, read the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects available at www.medsafe.govt.nz or on request from Merck Sharp & Dohme (New Zealand) Limited. Prescription Only Medicine. Indication: As monotherapy for the treatment of unresectable or metastatic melanoma in adults. In combination with platinum-pemetrexed for first-line treatment of metastatic non-squamous NSCLC. As monotherapy for first-line treatment of patients with metastatic NSCLC whose tumours express PD-L1 ≥50% tumour proportion score (TPS) on a validated test, with no EGFR or ALK genomic tumour aberrations. As monotherapy for the treatment of patients with advanced NSCLC with a PD-L1 TPS level ≥1% 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 refractory/ relapsed classical Hodgkin Lymphoma (cHL). As monotherapy for patients with locally advanced/ metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy, or who have received platinum-containing chemotherapy. See full data sheet. **Contraindications:** None. **Precautions:** Immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, nephritis, hypophysitis, type 1 diabetes mellitus, hyperthyroidism, hypothyroidism, thyroiditis, uveitis, myositis, Guillain-Barre syndrome, pancreatitis, encephalitis, sarcoidosis, myasthenic syndrome, severe skin reactions (including Stevens-Johnson syndrome and toxic epidermal necrolysis), and severe infusion reactions including hypersensitivity and anaphylaxis. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. For management of immune-mediated adverse events, see full data sheet. Limited information in patients with active infection and patients with on-going adverse reaction to ipilimumab – use caution. Acute graft-versus-host-disease in patients with history of allogeneic HSCT. Post-marketing: solid organ transplant rejection and myocarditis. See full data sheet for further information. **Interactions:** None expected. Avoid corticosteroids or immunosuppressants prior to treatment. **Side effects:** Clinical trials (treatment-related only): nasopharyngitis, anaemia, hypothyroidism, decreased appetite, dizziness, headache, cough, dyspnea, abdominal pain, constipation, diarrhea, nausea, vomiting, erythema, pruritus, rash, vitiligo, arthralgia, back pain, myalgia, pain in extremity, asthenia, chills, fatigue, oedema peripheral, pyrexia, colitis, hepatitis, hyperthyroidism, hypophysitis, nephritis, pneumonitis, type 1 diabetes mellitus, adrenal insufficiency, autoimmune hepatitis, alopecia, upper respiratory tract infection. **Dosage and administration:** The recommended dose of KEYTRUDA is 200 mg for previously untreated NSCLC, cHL, and urothelial carcinoma, and 2 mg/kg or 200 mg for melanoma or previously treated NSCLC (administered as an intravenous infusion over 30 minutes every 3 weeks). KEYTRUDA should be administered first when given in combination with pemetrexed and carboplatin. 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. See full data sheet for further information, including details on PD-L1 testing KEYTRUDA is a funded medicine for melanoma patients– restrictions apply. KEYTRUDA is a private purchase medicine for NSCLC, cHL and urothelial carcinoma patients. Based on data sheet prepared 16 October 2017.
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