DOSING AND TESTING REQUIREMENTS

KEYTRUDA®
(pembrolizumab) Injection 100 mg

SELECTED SAFETY INFORMATION FOR *KEYTRUDA*

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or the programmed death ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, can affect more than one body system simultaneously, and can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions.
- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti–PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. For patients with TNBC treated with KEYTRUDA in the neoadjuvant setting, monitor blood cortisol at baseline, prior to surgery, and as clinically indicated. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

TNBC=triple-negative breast cancer.

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide also is available.

SELECTED INDICATIONS FOR *KEYTRUDA*

- KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic melanoma.
- KEYTRUDA is indicated for the adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIB, IIC, or III melanoma following complete resection.
- KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic nonsquamous non–small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
- KEYTRUDA, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of patients with metastatic squamous NSCLC.
- KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with NSCLC expressing PD-L1 [tumor proportion score (TPS) ≥1%] as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and is stage III where patients are not candidates for surgical resection or definitive chemoradiation, or metastatic.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA.
- KEYTRUDA is indicated for the treatment of patients with resectable (tumors ≥4 cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- KEYTRUDA, as a single agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥4 cm), II, or IIIA NSCLC.
- KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM).
- KEYTRUDA is indicated for the treatment of adult patients with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin and then as a single agent.
- KEYTRUDA, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC.
- KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.
- KEYTRUDA is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL).
- KEYTRUDA is indicated for the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy.
- KEYTRUDA is indicated for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after 2 or more prior lines of therapy. KEYTRUDA is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.
- KEYTRUDA, in combination with enfortumab vedotin, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer.

EGFR=epidermal growth factor receptor; ALK=anaplastic lymphoma kinase; FDA=Food and Drug Administration.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Pneumonitis

- KEYTRUDA can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (94/2799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (63/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) and withholding in 0.9% (26) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Pneumonitis resolved in 59% of the 94 patients.

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KEYTRUDA® (pembrolizumab) Injection 100 mg

SELECTED INDICATIONS FOR *KEYTRUDA* (*continued*)

- KEYTRUDA, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma:
  - who are not eligible for any platinum-containing chemotherapy, or
  - who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.
- KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.
- KEYTRUDA is indicated for the treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-approved test.
- KEYTRUDA, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
- KEYTRUDA, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
- KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic esophageal or GEJ (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation either:
  - in combination with platinum- and fluoropyrimidine-based chemotherapy for patients with tumors that express PD-L1 (CPS ≥1), or
  - as a single agent after one or more prior lines of systemic therapy for patients with tumors of squamous cell histology that express PD-L1 (CPS ≥10) as determined by an FDA-approved test.
- KEYTRUDA, in combination with chemoradiotherapy (CRT), is indicated for the treatment of patients with locally advanced cervical cancer involving the lower third of the vagina, with or without extension to pelvic sidewall, or hydronephrosis/non-functioning kidney, or spread to adjacent pelvic organs (FIGO 2014 Stage III-IVA).
- KEYTRUDA, in combination with chemotherapy, with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test.
- KEYTRUDA is indicated for the treatment of patients with hepatocellular carcinoma (HCC) secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1–containing regimen.
- KEYTRUDA, in combination with gemcitabine and cisplatin, is indicated for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC).

HER2=human epidermal growth factor receptor 2;
FIGO=International Federation of Gynecology and Obstetrics.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Pneumonitis (*continued*)

- Pneumonitis occurred in 8% (31/389) of adult patients with cHL receiving KEYTRUDA as a single agent, including Grades 3-4 in 2.3% of patients. Patients received high-dose corticosteroids for a median duration of 10 days (range: 2 days to 53 months). Pneumonitis rates were similar in patients with and without prior thoracic radiation. Pneumonitis led to discontinuation of KEYTRUDA in 5.4% (21) of patients. Of the patients who developed pneumonitis, 42% interrupted KEYTRUDA, 68% discontinued KEYTRUDA, and 77% had resolution.
- Pneumonitis occurred in 7% (41/580) of adult patients with resected NSCLC who received KEYTRUDA as a single agent for adjuvant treatment of NSCLC, including fatal (0.2%), Grade 4 (0.3%), and Grade 3 (1%) adverse reactions. Patients received high-dose corticosteroids for a median duration of 10 days (range: 1 day to 2.3 months). Pneumonitis led to discontinuation of KEYTRUDA in 26 (4.5%) of patients. Of the patients who developed pneumonitis, 54% interrupted KEYTRUDA, 63% discontinued KEYTRUDA, and 71% had resolution.

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SELECTED INDICATIONS FOR *KEYTRUDA* (*continued*)

- KEYTRUDA is indicated for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC).
- KEYTRUDA, in combination with axitinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).
- KEYTRUDA is indicated for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
- KEYTRUDA, in combination with carboplatin and paclitaxel, followed by KEYTRUDA as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.
- KEYTRUDA, as a single agent, is indicated for the treatment of adult patients with advanced endometrial carcinoma that is MSI-H or dMMR, as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
- KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC that is not curable by surgery or radiation.
- KEYTRUDA is indicated for the treatment of patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.
- KEYTRUDA, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-approved test.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Colitis

- KEYTRUDA can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 1.7% (48/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 69% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients.

Hepatotoxicity and Immune-Mediated Hepatitis

KEYTRUDA as a Single Agent

- KEYTRUDA can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients.

KEYTRUDA With Axitinib

- KEYTRUDA in combination with axitinib can cause hepatic toxicity. Monitor liver enzymes before initiation of and periodically throughout treatment. Consider monitoring more frequently as compared to when the drugs are administered as single agents. For elevated liver enzymes, interrupt KEYTRUDA and axitinib, and consider administering corticosteroids as needed. With the combination of KEYTRUDA and axitinib, Grades 3 and 4 increased alanine aminotransferase (ALT) (20%) and increased aspartate aminotransferase (AST) (13%) were seen at a higher frequency compared to KEYTRUDA alone. Fifty-nine percent of the patients with increased ALT received systemic corticosteroids. In patients with ALT ≥3 times upper limit of normal (ULN) (Grades 2-4, n=116), ALT resolved to Grades 0-1 in 94%. Among the 92 patients who were rechallenged with either KEYTRUDA (n=3) or axitinib (n=34) administered as a single agent or with both (n=55), recurrence of ALT ≥3 times ULN was observed in 1 patient receiving KEYTRUDA, 16 patients receiving axitinib, and 24 patients receiving both. All patients with a recurrence of ALT ≥3 ULN subsequently recovered from the event.

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DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA*

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
NSCLC	**First-Line Metastatic Nonsquamous NSCLC in Combination With Pemetrexed and Platinum Chemotherapy**	No testing for PD-L1 EGFR and ALK negative	Fixed 200 mg	Over **30 minutes** every **3 weeks**[a]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[a]	
	First-Line Metastatic Squamous NSCLC in Combination With Carboplatin and Either Paclitaxel or Paclitaxel Protein-Bound	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[a]	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[a]	
	First-Line Advanced or Metastatic NSCLC	PD-L1 expression (TPS ≥1%)[b] EGFR and ALK negative	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	Second-Line or Greater Metastatic NSCLC	PD-L1 expression (TPS ≥1%)[b] If EGFR or ALK positive, should have disease progression on FDA-approved therapy for these aberrations	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	

[a]When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
[b]Tumor proportion score (TPS) as determined by an FDA-approved test.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

See pages 6 to 12 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA depending on severity. Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Hypophysitis

- KEYTRUDA can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

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KEYTRUDA® (pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA* (*continued*)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
 NSCLC	**Resectable (Tumors ≥4 cm or Node Positive) NSCLC in Combination With Platinum-Containing Chemotherapy as Neoadjuvant Treatment, and Then Continued as a Single Agent as Adjuvant Treatment After Surgery**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[a]	Neoadjuvant treatment in combination with chemotherapy for 12 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as a single agent after surgery for 39 weeks or until disease recurrence or unacceptable toxicity.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[a]	
	Adjuvant Treatment Following Resection and Platinum-Based Chemotherapy for Adult Patients With Stage IB (T2a ≥4 cm), II, or IIIA NSCLC	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease recurrence, unacceptable toxicity, or up to 12 months.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
 MPM	**First-Line Treatment of Adult Patients With Unresectable Advanced or Metastatic MPM in Combination With Pemetrexed and Platinum Chemotherapy**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[a]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[a]	
 Advanced RCC	**First-Line Advanced RCC in Combination With Axitinib**	No	Fixed 200 mg in combination with 5 mg axitinib orally twice daily	Over **30 minutes** every **3 weeks**	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression. When axitinib is used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5-mg dose may be considered at intervals of 6 weeks or longer.
			Fixed 400 mg in combination with 5 mg axitinib orally twice daily	Over **30 minutes** every **6 weeks**	
	Adjuvant Treatment of Patients With RCC at Intermediate-High or High Risk of Recurrence Following Nephrectomy, or Following Nephrectomy and Resection of Metastatic Lesions	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease recurrence, unacceptable toxicity, or up to 12 months.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	

[a]When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

See pages 7 to 12 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders

- KEYTRUDA can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Thyroiditis occurred in 0.6% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.

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KEYTRUDA® (pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA* (*continued*)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
 **Advanced MSI-H/dMMR cancers**	**Adult Patients With Previously Treated Advanced MSI-H or dMMR Cancer**	MSI or MMR[a]	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	Pediatric Patients With Previously Treated Advanced MSI-H or dMMR Cancer	MSI or MMR[a]	2 mg/kg (up to a maximum of 200 mg)	Over **30 minutes** every **3 weeks**	
 **Advanced MSI-H/dMMR CRC**	**Advanced MSI-H or dMMR CRC**	MSI or MMR[a]	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
 **Refractory or relapsed cHL**	**Adult Patients With Relapsed or Refractory cHL**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
	Pediatric Patients With Relapsed or Refractory cHL		2 mg/kg (up to a maximum of 200 mg)	Over **30 minutes** every **3 weeks**	
 **Refractory or relapsed PMBCL**	**Adult Patients With Refractory or Relapsed PMBCL**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
	Pediatric Patients With Refractory or Relapsed PMBCL	No	2 mg/kg (up to a maximum of 200 mg)	Over **30 minutes** every **3 weeks**	

[a]MSI or MMR, as determined by an FDA-approved test.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

See pages 8 to 12 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders (*continued*)

- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (237/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long-term thyroid hormone replacement. The incidence of new or worsening hypothyroidism was higher in 1185 patients with HNSCC, occurring in 16% of patients receiving KEYTRUDA as a single agent or in combination with platinum and FU, including Grade 3 (0.3%) hypothyroidism. The incidence of new or worsening hypothyroidism was higher in 389 adult patients with cHL (17%) receiving KEYTRUDA as a single agent, including Grade 1 (6.2%) and Grade 2 (10.8%) hypothyroidism. The incidence of new or worsening hyperthyroidism was higher in 580 patients with resected NSCLC, occurring in 11% of patients receiving KEYTRUDA as a single agent as adjuvant treatment, including Grade 3 (0.2%) hyperthyroidism. The incidence of new or worsening hypothyroidism was higher in 580 patients with resected NSCLC, occurring in 22% of patients receiving KEYTRUDA as a single agent as adjuvant treatment (KEYNOTE-091), including Grade 3 (0.3%) hypothyroidism.

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KEYTRUDA® (pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA* (*continued*)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
HNSCC	**Adult Patients With Resectable Locally Advanced HNSCC as Neoadjuvant Treatment, and Then Continued in Combination With RT With or Without Cisplatin as Adjuvant Treatment, and Then Continued as a Single Agent[a]**	PD-L1 expression (CPS ≥1)[b]	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Neoadjuvant: • Administer KEYTRUDA for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity. Adjuvant: • Administer KEYTRUDA in combination with RT with or without cisplatin. • Continue KEYTRUDA as a single agent. • Continue KEYTRUDA until disease recurrence or unacceptable toxicity or up to one year.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	First-Line Treatment of Metastatic or Unresectable, Recurrent HNSCC in Combination With Platinum and FU	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[c]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[c]	
	First-Line Treatment of Metastatic or Unresectable, Recurrent HNSCC	PD-L1 expression (CPS ≥1)[b]	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	Second-Line Treatment of Metastatic or Recurrent HNSCC	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
Advanced urothelial cancer	**Adult Patients With Locally Advanced or Metastatic Urothelial Cancer in Combination With Enfortumab Vedotin**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[d]	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[d]	
	Locally Advanced or Metastatic Urothelial Carcinoma	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	Second-Line Locally Advanced or Metastatic Urothelial Carcinoma	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	

[a]Administer KEYTRUDA prior to cisplatin when given on the same day.
[b]CPS as determined by an FDA-approved test.
[c]When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
[d]When administering KEYTRUDA in combination with enfortumab vedotin, administer KEYTRUDA after enfortumab vedotin when given on the same day. Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

See pages 9 to 12 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Endocrinopathies (*continued*)

Type 1 Diabetes Mellitus (DM), Which Can Present With Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA depending on severity. Type 1 DM occurred in 0.2% (6/2799) of patients receiving KEYTRUDA. It led to permanent discontinuation in <0.1% (1) and withholding of KEYTRUDA in <0.1% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

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KEYTRUDA® (pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA* (*continued*)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
 **High-risk NMIBC**	**BCG-Unresponsive, High-Risk NMIBC Patients With CIS Who Are Ineligible for/ Have Refused Cystectomy**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
 **Advanced gastric or GEJ adenocarcinoma**	**First-Line Treatment of Adults With Advanced Unresectable or Metastatic HER2-Positive Gastric or GEJ Adenocarcinoma in Combination With Trastuzumab, Fluoropyrimidine- and Platinum-Containing Chemotherapy**	HER2 Status PD-L1 expression (CPS ≥1)[a]	Fixed 200 mg	Over **30 minutes** every **3 weeks**[b]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[b]	
	First-Line Treatment of Adults With Locally Advanced Unresectable or Metastatic HER2-Negative Gastric or GEJ Adenocarcinoma in Combination With Fluoropyrimidine- and Platinum-Containing Chemotherapy	HER2 Status PD-L1 expression (CPS ≥1)[a]	Fixed 200 mg	Over **30 minutes** every **3 weeks**[c]	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[c]	
 **Advanced esophageal or GEJ carcinoma**	**First-Line Locally Advanced or Metastatic Carcinoma of the Esophagus or GEJ (Tumors With Epicenter 1 to 5 Centimeters Above the GEJ) in Combination With Platinum- and Fluoropyrimidine-Based Chemotherapy**	PD-L1 expression (CPS ≥1)[a]	Fixed 200 mg	Over **30 minutes** every **3 weeks**[c]	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[c]	
	Second-Line or Greater Locally Advanced or Metastatic Squamous Cell Carcinoma of the Esophagus or GEJ (Tumors With Epicenter 1 to 5 Centimeters Above the GEJ)	PD-L1 expression (CPS ≥10)[a]	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	

[a]CPS as determined by an FDA-approved test.
[b]When administering KEYTRUDA in combination with trastuzumab and chemotherapy, administer KEYTRUDA prior to trastuzumab and chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
[c]When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

See pages 10 to 12 for requirements for additional indications.

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.3% (9/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (8/9) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (3) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide also is available.

KEYTRUDA® (pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA* (*continued*)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
 **Advanced cervical cancer**	**First-Line Treatment of Patients With FIGO 2014 Stage III-IVA Cervical Cancer in Combination With CRT**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[a]	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[a]	
	First-Line Persistent, Recurrent, or Metastatic Cervical Cancer in Combination With Chemotherapy With or Without Bevacizumab	PD-L1 expression (CPS ≥1)[b]	Fixed 200 mg	Over **30 minutes** every **3 weeks**[a]	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[a]	
	Second-Line Recurrent or Metastatic Cervical Cancer	PD-L1 expression (CPS ≥1)[b]	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
 **HCC**	**Treatment of Patients With HCC Secondary to Hepatitis B Who Have Received Prior Systemic Therapy Other Than a PD-1/PD-L1–Containing Regimen**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
 **Advanced BTC**	**Locally Advanced Unresectable or Metastatic BTC in Combination With Gemcitabine and Cisplatin**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[c]	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[c]	
 **Advanced MCC**	**Adult Patients With Recurrent Locally Advanced or Metastatic Merkel Cell Carcinoma**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	Pediatric Patients With Recurrent Locally Advanced or Metastatic Merkel Cell Carcinoma	No	2 mg/kg (up to a maximum of 200 mg)	Over **30 minutes** every **3 weeks**	

[a]When administering KEYTRUDA in combination with chemoradiotherapy or chemotherapy with or without bevacizumab, administer KEYTRUDA prior to chemoradiotherapy or prior to chemotherapy with or without bevacizumab when given on the same day. Refer to the Prescribing Information for bevacizumab and for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
[b]CPS as determined by an FDA-approved test.
[c]When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

See pages 11 and 12 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti–PD-1/PD-L1 treatments. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonexfoliative rashes. Withhold or permanently discontinue KEYTRUDA depending on severity. Immune-mediated dermatologic adverse reactions occurred in 1.4% (38/2799) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 40% (15/38) of patients. These reactions led to permanent discontinuation in 0.1% (2) and withholding of KEYTRUDA in 0.6% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients.

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide also is available.

KEYTRUDA® (pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA* (*continued*)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
 **Advanced cSCC**	**Recurrent or Metastatic cSCC or Locally Advanced cSCC That Is Not Curable by Surgery or Radiation**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
 **Melanoma**	**Adult Patients With Unresectable or Metastatic Melanoma**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease progression or unacceptable toxicity.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	Adjuvant Treatment of Adult Patients With Stage IIB, IIC, or III Melanoma Following Complete Resection	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease recurrence, unacceptable toxicity, or up to 12 months.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
	Adjuvant Treatment of Pediatric (12 years and older) Patients With Stage IIB, IIC, or III Melanoma Following Complete Resection	No	2 mg/kg (up to a maximum of 200 mg)	Over **30 minutes** every **3 weeks**	

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

See page 12 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA or were reported with the use of other anti–PD-1/PD-L1 treatments. Severe or fatal cases have been reported for some of these adverse reactions. *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis; *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; *Ocular*: Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss; *Gastrointestinal*: Pancreatitis, to include increases in serum amylase and lipase levels, gastritis, duodenitis; *Musculoskeletal and Connective Tissue*: Myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis (1.5%), polymyalgia rheumatica; *Endocrine*: Hypoparathyroidism; *Hematologic/Immune*: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

- KEYTRUDA can cause severe or life-threatening infusion-related reactions, including hypersensitivity and anaphylaxis, which have been reported in 0.2% of 2799 patients receiving KEYTRUDA. Monitor for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA.

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide also is available.

KEYTRUDA® (pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR *KEYTRUDA* (*continued*)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
 **Endometrial Carcinoma**	**Primary Advanced or Recurrent Endometrial Carcinoma in Combination With Carboplatin and Paclitaxel, Followed By Treatment as a Single Agent**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[a]	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[a]	
	Advanced Endometrial Carcinoma That Is MSI-H or dMMR, Who Have Disease Progression Following Prior Systemic Therapy in Any Setting and Are Not Candidates for Curative Surgery or Radiation	MSI or MMR[b]	Fixed 200 mg	Over **30 minutes** every **3 weeks**	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**	
 **TNBC**	**High-Risk Early-Stage TNBC in Combination With Chemotherapy as Neoadjuvant Treatment, and Then Continued as a Single Agent as Adjuvant Treatment After Surgery**	No	Fixed 200 mg	Over **30 minutes** every **3 weeks**[c]	Treatment should start as neoadjuvant treatment in combination with chemotherapy for 24 weeks (8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks) or until disease progression or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as a single agent for up to 27 weeks (9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks) or until disease recurrence or unacceptable toxicity.[d]
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[c]	
	Locally Recurrent Unresectable or Metastatic TNBC in Combination With Chemotherapy	PD-L1 expression (CPS ≥10)[e]	Fixed 200 mg	Over **30 minutes** every **3 weeks**[c]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			Fixed 400 mg	Over **30 minutes** every **6 weeks**[c]	

[a]Administer KEYTRUDA prior to carboplatin and paclitaxel when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
[b]MSI or MMR, as determined by an FDA-approved test.
[c]When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
[d]Patients who experience disease progression that precludes definitive surgery or unacceptable toxicity related to KEYTRUDA with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single-agent KEYTRUDA.
[e]CPS as determined by an FDA-approved test.

See full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after anti–PD-1/PD-L1 treatments. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between anti–PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients closely for evidence of these complications and intervene promptly. Consider the benefit vs risks of using anti–PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti–PD-1/PD-L1 treatment in this combination is not recommended outside of controlled trials.

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide also is available.

KEYTRUDA® (pembrolizumab) Injection 100 mg

SELECTED SAFETY INFORMATION FOR *KEYTRUDA* (*continued*)

Embryofetal Toxicity

- Based on its mechanism of action, KEYTRUDA can cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. In females of reproductive potential, verify pregnancy status prior to initiating KEYTRUDA and advise them to use effective contraception during treatment and for 4 months after the last dose.

Adverse Reactions

- When KEYTRUDA was used as monotherapy, the most common adverse reactions (≥20%) were fatigue, musculoskeletal pain, rash, diarrhea, pyrexia, cough, decreased appetite, pruritus, dyspnea, constipation, pain, abdominal pain, nausea, and hypothyroidism.
- When KEYTRUDA was used in combination with chemotherapy or chemoradiotherapy the most common adverse reactions (≥20%) were fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, pyrexia, alopecia, peripheral neuropathy, mucosal inflammation, stomatitis, headache, weight loss, abdominal pain, arthralgia, myalgia, insomnia, palmar-plantar erythrodysesthesia, urinary tract infection, hypothyroidism, radiation skin injury, dysphagia, dry mouth, and musculoskeletal pain.
- When KEYTRUDA was used in combination with chemotherapy and bevacizumab, the most common adverse reactions (≥20%) were peripheral neuropathy, alopecia, anemia, fatigue/asthenia, nausea, neutropenia, diarrhea, hypertension, thrombocytopenia, constipation, arthralgia, vomiting, urinary tract infection, rash, leukopenia, hypothyroidism, and decreased appetite.
- When KEYTRUDA was used in combination with axitinib, the most common adverse reactions (≥20%) were diarrhea, fatigue/asthenia, hypertension, hepatotoxicity, hypothyroidism, decreased appetite, palmar-plantar erythrodysesthesia, nausea, stomatitis/mucosal inflammation, dysphonia, rash, cough, and constipation.
- When KEYTRUDA was used in combination with enfortumab vedotin, the most common adverse reactions (≥20%) were rash, peripheral neuropathy, fatigue, pruritus, diarrhea, alopecia, weight loss, decreased appetite, nausea, constipation, dry eye, dysgeusia, and urinary tract infection.

Lactation

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

Pediatric Use

- In KEYNOTE-051, 173 pediatric patients (65 pediatric patients aged 6 months to younger than 12 years and 108 pediatric patients aged 12 years to 17 years) were administered KEYTRUDA 2 mg/kg every 3 weeks. The median duration of exposure was 2.1 months (range: 1 day to 25 months).
- Adverse reactions that occurred at a ≥10% higher rate in pediatric patients when compared to adults were pyrexia (33%), leukopenia (30%), vomiting (29%), neutropenia (28%), headache (25%), abdominal pain (23%), thrombocytopenia (22%), Grade 3 anemia (17%), decreased lymphocyte count (13%), and decreased white blood cell count (11%).

Geriatric Use

- Of the 564 patients with locally advanced or metastatic urothelial cancer treated with KEYTRUDA in combination with enfortumab vedotin, 44% (n=247) were 65-74 years and 26% (n=144) were 75 years or older. No overall differences in safety or effectiveness were observed between patients 65 years of age or older and younger patients. Patients 75 years of age or older treated with KEYTRUDA in combination with enfortumab vedotin experienced a higher incidence of fatal adverse reactions than younger patients. The incidence of fatal adverse reactions was 4% in patients younger than 75 and 7% in patients 75 years or older.

Before prescribing KEYTRUDA, please read the accompanying Prescribing Information. The Medication Guide also is available.

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