

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) $\geq 1\%$] as determined by an FDA-authorized 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 $\geq 1\%$) as determined by an FDA-authorized 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-authorized 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-authorized 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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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, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC) who are ineligible for cisplatin-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-authorized 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-authorized 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-authorized 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-authorized 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-authorized 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-authorized 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-authorized 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.

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, in combination with gemcitabine and cisplatin, is indicated for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC).
- 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-authorized 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-authorized test.
- KEYTRUDA, in combination with paclitaxel, with or without bevacizumab, is indicated for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-authorized test, and who have received 1 or 2 prior systemic treatment regimens.

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	

^aWhen 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.

^bTPS as determined by an FDA-authorized test.

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

See pages 6 to 13 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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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	
 MPM	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	
 Advanced RCC	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	

^aWhen 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 7 to 13 for requirements for additional indications.

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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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	No	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	
	Pediatric Patients With Refractory or Relapsed PMBCL	No	2 mg/kg (up to a maximum of 200 mg)	Over 30 minutes every 3 weeks	

^aMSI or MMR, as determined by an FDA-authorized test.

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See pages 8 to 13 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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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 \geq 1) ^b	Fixed 200 mg	Over 30 minutes every 3 weeks	Neoadjuvant: <ul style="list-style-type: none"> Administer KEYTRUDA for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity.
			Fixed 400 mg	Over 30 minutes every 6 weeks	Adjuvant: <ul style="list-style-type: none"> 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.
	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 \geq 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		

^aAdminister KEYTRUDA prior to cisplatin when given on the same day.

^bCPS as determined by an FDA-authorized test.

^cWhen 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.

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See pages 9 to 13 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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DOSING AND TESTING REQUIREMENTS FOR KEYTRUDA (continued)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment
 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 ^a	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 ^a	
	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		
 MIBC	Adult Patients With MIBC Ineligible for Cisplatin-Containing Chemotherapy in Combination With Enfortumab Vedotin as Neoadjuvant Treatment, and Then Continued After Cystectomy as Adjuvant Treatment	No	Neoadjuvant: 200 mg	Over 30 minutes every 3 weeks ^a	Neoadjuvant: • Administer KEYTRUDA 200 mg every 3 weeks for 3 doses in combination with enfortumab vedotin or until disease progression that precludes curative-intent cystectomy or unacceptable toxicity. Adjuvant: • Administer KEYTRUDA 200 mg every 3 weeks for 14 doses or 400 mg every 6 weeks for 7 doses in combination with enfortumab vedotin or until disease recurrence or unacceptable toxicity
			+		
			Adjuvant: Fixed 200 mg	Over 30 minutes every 3 weeks ^a	
	Or		Adjuvant: Fixed 400 mg	Over 30 minutes every 6 weeks ^a	
 High-risk NMIBC	BCG-Unresponsive, High-Risk NMIBC Patients With CIS With or Without Papillary Tumors 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	

^aWhen 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 10 to 13 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR KEYTRUDA (continued)

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 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	
 Advanced esophageal or GEJ carcinoma	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	
	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		

^aCPS as determined by an FDA-authorized test.

^bWhen 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.

^cWhen 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 to 13 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 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,b}	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months.
	First-Line Persistent, Recurrent, or Metastatic Cervical Cancer in Combination With Chemotherapy With or Without Bevacizumab	PD-L1 expression (CPS ≥ 1) ^c	Fixed 200 mg	Over 30 minutes every 3 weeks ^{a,b}	
			Fixed 400 mg	Over 30 minutes every 6 weeks ^{a,b}	
Second-Line Recurrent or Metastatic Cervical Cancer	PD-L1 expression (CPS ≥ 1) ^c	Fixed 200 mg	Over 30 minutes every 3 weeks	Over 30 minutes every 6 weeks	
		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	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	
 Advanced BTC	Locally Advanced Unresectable or Metastatic BTC in Combination With Gemcitabine and Cisplatin	No	Fixed 200 mg	Over 30 minutes every 3 weeks ^{b,d}	
			Fixed 400 mg	Over 30 minutes every 6 weeks ^{b,d}	

^aWhen 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.

^bRefer to the Prescribing Information for bevacizumab and for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

^cCPS as determined by an FDA-authorized test.

^dWhen administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day.

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

See pages 12 and 13 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.

Before prescribing KEYTRUDA, please read the accompanying [Prescribing Information](#). The [Medication Guide](#) also is available.

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(pembrolizumab) Injection 100 mg

DOSING AND TESTING REQUIREMENTS FOR KEYTRUDA (continued)

Tumor Type	Indication	Testing	Dose	Intravenous Infusion After Dilution	Duration of Treatment	
 Advanced MCC	Adult Patients With Recurrent Locally Advanced or Metastatic Merkel Cell Carcinoma	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		
 Advanced cSCC	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		
	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		
 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		
 Melanoma	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 13 for requirements for additional indications.

SELECTED SAFETY INFORMATION FOR KEYTRUDA (continued)

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.

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

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,b}	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months.
			Fixed 400 mg	Over 30 minutes every 6 weeks ^{a,b}	
 TNBC	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 ^c	Fixed 200 mg	Over 30 minutes every 3 weeks	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			Fixed 400 mg	Over 30 minutes every 6 weeks	
 Ovarian Cancer	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 ^{b,d}	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. ^e
			Fixed 400 mg	Over 30 minutes every 6 weeks ^{b,d}	
 Ovarian Cancer	Locally Recurrent Unresectable or Metastatic TNBC in Combination With Chemotherapy	PD-L1 expression (CPS ≥ 10) ^f	Fixed 200 mg	Over 30 minutes every 3 weeks ^{b,d}	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			Fixed 400 mg	Over 30 minutes every 6 weeks ^{b,d}	
 Ovarian Cancer	Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma in Combination With Paclitaxel, With or Without Bevacizumab, in Adult Patients Who Have Received One or Two Prior Systemic Treatment Regimens	PD-L1 expression (CPS ≥ 1) ^f	Fixed 200 mg	Over 30 minutes every 3 weeks ^{b,g}	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			Fixed 400 mg	Over 30 minutes every 6 weeks ^{b,g}	

^aAdminister KEYTRUDA prior to carboplatin and paclitaxel when given on the same day.

^bRefer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.

^cMSI or MMR, as determined by an FDA-authorized test.

^dWhen administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day.

^ePatients who experience disease progression or unacceptable toxicity related to KEYTRUDA with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single-agent KEYTRUDA.

^fCPS as determined by an FDA-authorized test.

^gAdminister KEYTRUDA prior to paclitaxel with or without bevacizumab when given on the same day.

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

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.

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)

Adverse Reactions

- When KEYTRUDA was used as monotherapy, the most common adverse reactions ($\geq 20\%$) 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 ($\geq 20\%$) 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 ($\geq 20\%$) were peripheral neuropathy, alopecia, anemia, fatigue/asthenia, nausea, neutropenia, diarrhea, hypertension, thrombocytopenia, constipation, arthralgia, vomiting, urinary tract infection, rash, leukopenia, hypothyroidism, decreased appetite, pyrexia, epistaxis, decreased white blood cell count, and stomatitis.
- When KEYTRUDA was used in combination with axitinib, the most common adverse reactions ($\geq 20\%$) 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 ($\geq 20\%$) 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 $\geq 10\%$ 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 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.
- Of the 167 patients with MIBC treated with KEYTRUDA in combination with enfortumab vedotin, 37% (n=61) were 65-74 years and 46% (n=77) were 75 years or older. 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 12% 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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