KEYTRUDA Qlex™

pembrolizumab + berahyaluronidase alfa-pmph

Subcutaneous Injection | 165 mg + 2,000 units/mL



DOSING, TESTING & ADMINISTRATION GUIDE

SELECTED SAFETY INFORMATION

Contraindications

- KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to berahyaluronidase alfa, hyaluronidase or to any of its excipients.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA QLEX 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 QLEX 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.

TNBC= triple-negative breast cancer.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA QLEX is FDA-approved for 17 types of cancer, including certain early-stage and advanced cancers

SELECTED INDICATIONS FOR KEYTRUDA QLEX

- KEYTRUDA QLEX is indicated for the treatment of adult patients with unresectable or metastatic melanoma.
- KEYTRUDA QLEX is indicated for the adjuvant treatment of adult and pediatric patients 12 years and older with stage IIB, IIC, or III melanoma following complete resection.
- KEYTRUDA QLEX, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of adult patients with metastatic nonsquamous non–small cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- KEYTRUDA QLEX, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of adult patients with metastatic squamous NSCLC.
- KEYTRUDA QLEX, as a single agent, is indicated for the first-line treatment of adult patients with NSCLC expressing PD-L1 [tumor proportion score (TPS) ≥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 QLEX, as a single agent, is indicated for the treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥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 QLEX.
- KEYTRUDA QLEX is indicated for the treatment of adult 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 QLEX, 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 QLEX, 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).

SELECTED SAFETY INFORMATION *(continued)*

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

- Withhold or permanently discontinue KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA QLEX 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.

Immune-Mediated Pneumonitis

- KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 5% (13/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including fatal (0.4%), Grade 3 (2%), and Grade 2 (1.2%) adverse reactions.

Intravenous Pembrolizumab as a Single Agent

- Immune-mediated pneumonitis occurred in 3.4% (94/2799) of patients receiving intravenous pembrolizumab, 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 intravenous pembrolizumab in 1.3% (36) and withholding in 0.9% (26) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement; of these, 23% had recurrence. Pneumonitis resolved in 59% of the 94 patients.

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SELECTED INDICATIONS FOR KEYTRUDA QLEX *(continued)*

- KEYTRUDA QLEX 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 QLEX, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of adult patients with metastatic or with unresectable, recurrent HNSCC.
- KEYTRUDA QLEX, as a single agent, is indicated for the first-line treatment of adult patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
- KEYTRUDA QLEX, as a single agent, is indicated for the treatment of adult patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.
- KEYTRUDA QLEX, in combination with enfortumab vedotin-ejfv, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer.
- KEYTRUDA QLEX, as a single agent, is indicated for the treatment of adult 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 QLEX, in combination with enfortumab vedotin-ejfv, 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).
- KEYTRUDA QLEX, as a single agent, is indicated for the treatment of adult 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 QLEX is indicated for the treatment of adult and pediatric patients 12 years and older 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 QLEX is indicated for the treatment of adult patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-authorized test.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Pneumonitis (*continued*)

Intravenous Pembrolizumab as a Single Agent (continued)

- Pneumonitis occurred in 7% (41/580) of adult patients with resected NSCLC who received intravenous pembrolizumab 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 intravenous pembrolizumab in 26 (4.5%) of patients. Of the patients who developed pneumonitis, 54% interrupted intravenous pembrolizumab, 63% discontinued intravenous pembrolizumab, and 71% had resolution.

Immune-Mediated Colitis

- KEYTRUDA QLEX 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 1.2% (3/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

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SELECTED INDICATIONS FOR KEYTRUDA QLEX *(continued)*

- KEYTRUDA QLEX, 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 QLEX, 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 gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
- KEYTRUDA QLEX is indicated for the treatment of adult patients with locally advanced or metastatic esophageal or gastroesophageal junction (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) as determined by an FDA-authorized test, 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 QLEX, in combination with chemoradiotherapy (CRT), is indicated for the treatment of adult 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 QLEX, in combination with chemotherapy, with or without bevacizumab, is indicated for the treatment of adult patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-authorized test.
- KEYTRUDA QLEX, as a single agent, is indicated for the treatment of adult 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 QLEX is indicated for the treatment of adult 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 QLEX, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult 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 *(continued)*

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

Immune-Mediated Colitis (*continued*)

Intravenous Pembrolizumab as a Single Agent

- Immune-mediated colitis occurred in 1.7% (48/2799) of patients receiving intravenous pembrolizumab, 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 intravenous pembrolizumab in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

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SELECTED INDICATIONS FOR KEYTRUDA QLEX *(continued)*

- KEYTRUDA QLEX is indicated for the treatment of adult and pediatric patients 12 years and older with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC).
- KEYTRUDA QLEX, in combination with axitinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).
- KEYTRUDA QLEX is indicated for the adjuvant treatment of adult patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
- KEYTRUDA QLEX, in combination with carboplatin and paclitaxel, followed by KEYTRUDA QLEX as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.
- KEYTRUDA QLEX, 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 QLEX is indicated for the treatment of adult patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC that is not curable by surgery or radiation.
- KEYTRUDA QLEX is indicated for the treatment of adult 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 QLEX, in combination with sacituzumab govitecan-hziy, is indicated for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-authorized test.
- KEYTRUDA QLEX, in combination with chemotherapy, is indicated for the treatment of adult patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) as determined by an FDA-authorized test.
- KEYTRUDA QLEX, 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 *(continued)*

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

Hepatotoxicity and Immune-Mediated Hepatitis *(continued)*

Intravenous Pembrolizumab as a Single Agent

- Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving intravenous pembrolizumab, 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 intravenous pembrolizumab in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients.

KEYTRUDA QLEX With Axitinib

- KEYTRUDA QLEX 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 QLEX and axitinib, and consider administering corticosteroids as needed.

Intravenous Pembrolizumab With Axitinib

- With the combination of intravenous pembrolizumab 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 intravenous pembrolizumab 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 intravenous pembrolizumab (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 intravenous pembrolizumab, 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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Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	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	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	First-Line Metastatic Squamous NSCLC in Combination With Carboplatin and Either Paclitaxel or Paclitaxel Protein-Bound	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	First-Line Advanced or Metastatic NSCLC	PD-L1 expression (TPS ≥1%)[c] EGFR and ALK negative	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	
	Second-Line or Greater Metastatic NSCLC	PD-L1 expression (TPS ≥1%)[c] If EGFR or ALK positive, should have disease progression on FDA-approved therapy for these aberrations	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.
[b]Administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.
[c]Tumor proportion score (TPS) as determined by an FDA-authorized test.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 2% (5/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

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Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	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	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	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 QLEX as a single agent after surgery for 39 weeks or until disease recurrence or unacceptable toxicity.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	Adjuvant Treatment Following Resection and Platinum-Based Chemotherapy for Adult Patients With Stage IB (T2a ≥4 cm), II, or IIIA NSCLC	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease recurrence, unacceptable toxicity, or up to 12 months.
			790 mg/9,600 units[a]	4.8 mL in 2 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	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

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

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SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

Adrenal Insufficiency *(continued)*

Intravenous Pembrolizumab as a Single Agent

- Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving intravenous pembrolizumab, 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 intravenous pembrolizumab in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement.

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Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 Advanced RCC	First-Line Advanced RCC in Combination With Axitinib	No	395 mg/4,800 units[a] in combination with 5 mg axitinib orally twice daily	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA QLEX, up to 24 months in patients without disease progression. When axitinib is used in combination with KEYTRUDA QLEX, dose escalation of axitinib above the initial 5-mg dose may be considered at intervals of 6 weeks or longer.
			790 mg/9,600 units[a] in combination with 5 mg axitinib orally twice daily	4.8 mL in 2 minutes every 6 weeks[b]	
	Adjuvant Treatment of Adult Patients With RCC at Intermediate-High or High Risk of Recurrence Following Nephrectomy, or Following Nephrectomy and Resection of Metastatic Lesions	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease recurrence, unacceptable toxicity, or up to 12 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

[b]Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate. See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

Hypophysitis

- KEYTRUDA QLEX 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 QLEX depending on severity.

Intravenous Pembrolizumab as a Single Agent

- Hypophysitis occurred in 0.6% (17/2799) of patients receiving intravenous pembrolizumab, 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 intravenous pembrolizumab in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement.

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Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 **Advanced MSI-H/dMMR cancers**	**Adult Patients With Previously Treated Unresectable or Metastatic MSI-H or dMMR Cancer**	MSI or MMR[a]	395 mg/4,800 units[b]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[b]	4.8 mL in 2 minutes every 6 weeks	
	Pediatric (12 years and older) Patients With Previously Treated Unresectable or Metastatic MSI-H or dMMR Cancer	MSI or MMR[a]	395 mg/4,800 units[b,c]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[b,c]	4.8 mL in 2 minutes every 6 weeks	
 **Advanced MSI-H/dMMR CRC**	**Unresectable or Metastatic MSI-H or dMMR CRC**	MSI or MMR[a]	395 mg/4,800 units[b]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[b]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

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

[b]mg of pembrolizumab/units of berahyaluronidase alfa.

[c]The recommended dosage for melanoma, MSI-H or dMMR, and MCC cancer has not been established in pediatric patients 12 years and older who weigh 40 kg or less.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders

- KEYTRUDA QLEX 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

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Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 High-risk NMIBC	BCG-Unresponsive, High-Risk NMIBC Patients With CIS Who Are Ineligible for/Have Refused Cystectomy	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	
 Advanced gastric or GEJ adenocarcinoma	First-Line Treatment of Adults With Locally 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)[b]	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[c]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[c]	
	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)[b]	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[c]	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[c]	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

[b]CPS as determined by an FDA-authorized test.

[c]Administer KEYTRUDA QLEX prior to chemotherapy and prior to trastuzumab when given on the same day. Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders (continued)

permanently discontinue KEYTRUDA QLEX depending on severity. Thyroiditis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hyperthyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (3.2%). Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 **Metastatic or unresectable, recurrent HNSCC**	**Resectable Locally Advanced HNSCC as a Single Agent as Neoadjuvant Treatment, and Then Continued as Adjuvant Treatment in Combination With Radiotherapy With or Without Cisplatin and Then as a Single Agent**	PD-L1 expression (CPS ≥1)[a]	395 mg/ 4,800 units[b]	2.4 mL in 1 minute every 3 weeks[c]	**Neoadjuvant**: Administer KEYTRUDA QLEX for 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity. **Adjuvant**: Administer KEYTRUDA QLEX in combination with RT ± cisplatin. Continue KEYTRUDA QLEX as a single agent. Continue KEYTRUDA QLEX until disease recurrence or unacceptable toxicity or up to one year.
			790 mg/ 9,600 units[b]	4.8 mL in 2 minutes every 6 weeks[c]	
	First-Line Metastatic or Unresectable, Recurrent HNSCC in Combination With Platinum and FU	No	395 mg/ 4,800 units[b]	2.4 mL in 1 minute every 3 weeks[d]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/ 9,600 units[b]	4.8 mL in 2 minutes every 6 weeks[d]	
	First-Line Metastatic or Unresectable, Recurrent HNSCC	PD-L1 expression (CPS ≥1)[a]	395 mg/ 4,800 units[b]	2.4 mL in 1 minute every 3 weeks	
			790 mg/ 9,600 units[b]	4.8 mL in 2 minutes every 6 weeks	
	Second-Line Metastatic or Recurrent HNSCC	No	395 mg/ 4,800 units[b]	2.4 mL in 1 minute every 3 weeks	
			790 mg/ 9,600 units[b]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]CPS as determined by an FDA-authorized test.

[b]mg of pembrolizumab/units of berahyaluronidase alpha.

[c]Administer KEYTRUDA QLEX prior to cisplatin when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

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

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders (continued)

Intravenous Pembrolizumab as a Single Agent

- Thyroiditis occurred in 0.6% (16/2799) of patients receiving intravenous pembrolizumab, including Grade 2 (0.3%). None discontinued, but intravenous pembrolizumab was withheld in <0.1% (1) of patients.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 Advanced urothelial cancer	Adult Patients With Locally Advanced or Metastatic Urothelial Cancer in Combination With Enfortumab Vedotin-ejfv	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	Locally Advanced or Metastatic Urothelial Carcinoma	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	
	Second-Line Locally Advanced or Metastatic Urothelial Carcinoma	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

[b]When administering KEYTRUDA QLEX in combination with enfortumab vedotin-ejfv, administer KEYTRUDA QLEX after enfortumab vedotin-ejfv when given on the same day. Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders (continued)

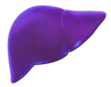
Intravenous Pembrolizumab as a Single Agent (continued)

- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving intravenous pembrolizumab, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of intravenous pembrolizumab in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement. Hypothyroidism occurred in 8% (237/2799) of patients receiving intravenous pembrolizumab, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of intravenous pembrolizumab in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated intravenous pembrolizumab 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 intravenous pembrolizumab as a single agent or in combination with platinum and FU, including Grade 3 (0.3%) hypothyroidism. The incidence of new or worsening hyperthyroidism was higher in 580 patients with resected NSCLC, occurring in 11% of patients receiving intravenous pembrolizumab 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 intravenous pembrolizumab as a single agent as adjuvant treatment (KEYNOTE-091), including Grade 3 (0.3%) hypothyroidism.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection[a]	Duration of Treatment
 Advanced cervical cancer	First-Line Treatment of Patients With FIGO 2014 Stage III-IVA Cervical Cancer in Combination With CRT	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA QLEX, up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	First-Line Persistent, Recurrent, or Metastatic Cervical Cancer in Combination With Chemotherapy With or Without Bevacizumab	PD-L1 expression (CPS ≥1)[c]	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	Second-Line Recurrent or Metastatic Cervical Cancer	PD-L1 expression (CPS ≥1)[c]	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 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	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen avoiding the 5 cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

[b]When administering KEYTRUDA QLEX in combination with chemoradiotherapy or chemotherapy with or without bevacizumab, administer KEYTRUDA QLEX 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 QLEX for recommended dosing information, as appropriate.

[c]CPS as determined by an FDA-authorized test.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

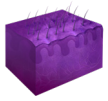
Type 1 Diabetes Mellitus (DM), Which Can Present With Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 Advanced cSCC	Recurrent or Metastatic cSCC or Locally Advanced cSCC That Is Not Curable by Surgery or Radiation	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	
 Melanoma	Adult Patients With Unresectable or Metastatic Melanoma	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease progression or unacceptable toxicity.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	
	Adjuvant Treatment of Adult Patients With Stage IIB, IIC, or III Melanoma Following Complete Resection	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease recurrence, unacceptable toxicity, or up to 12 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	
	Adjuvant Treatment of Pediatric (12 years and older) Patients With Stage IIB, IIC, or III Melanoma Following Complete Resection	No	395 mg/4,800 units[a,b]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a,b]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

[b]The recommended dosage for melanoma, MSI-H or dMMR, and MCC cancer has not been established in pediatric patients 12 years and older who weigh 40 kg or less.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies (*continued*)

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

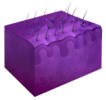
Intravenous Pembrolizumab as a Single Agent

- Type 1 DM occurred in 0.2% (6/2799) of patients receiving intravenous pembrolizumab. It led to permanent discontinuation in <0.1% (1) and withholding of intravenous pembrolizumab in <0.1% (1) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 Advanced BTC	Locally Advanced Unresectable or Metastatic BTC in Combination With Gemcitabine and Cisplatin	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
 Advanced MCC	Adult Patients With Recurrent Locally Advanced or Metastatic Merkel Cell Carcinoma	No	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	
	Pediatric Patients With Recurrent Locally Advanced or Metastatic Merkel Cell Carcinoma	No	395 mg/4,800 units[a,c]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[a,c]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

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

[c]The recommended dosage for melanoma, MSI-H or dMMR, and MCC cancer has not been established in pediatric patients 12 years and older who weigh 40 kg or less.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA QLEX can cause immune-mediated nephritis.

Intravenous Pembrolizumab as a Single Agent

- Immune-mediated nephritis occurred in 0.3% (9/2799) of patients receiving intravenous pembrolizumab, 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 intravenous pembrolizumab in 0.1% (3) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	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	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or for KEYTRUDA QLEX, up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	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]	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.

[b]Administer KEYTRUDA QLEX 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 QLEX for recommended dosing information, as appropriate.

[c]MSI or MMR, as determined by an FDA-authorized test.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA QLEX 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 QLEX depending on severity. Immune-mediated dermatologic adverse reactions occurred in 1.6% (4/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 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	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should start as neoadjuvant treatment in combination with chemotherapy for 24 weeks[c] or until disease progression or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA QLEX as a single agent for up to 27 weeks[d] or until disease recurrence or unacceptable toxicity.[e]
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	
	Unresectable Locally Advanced or Metastatic TNBC in Combination With Sacituzumab govitecan-hziy	PD-L1 expression (CPS ≥10)[f]	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[g]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[g]	
	Locally Recurrent Unresectable or Metastatic TNBC in Combination With Chemotherapy	PD-L1 expression (CPS ≥10)[f]	395 mg/4,800 units[a]	2.4 mL in 1 minute every 3 weeks[b]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[a]	4.8 mL in 2 minutes every 6 weeks[b]	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]mg of pembrolizumab/units of berahyaluronidase alfa.
[b]Administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.
[c]8 doses of 395 mg/4,800 units every 3 weeks or 4 doses of 790 mg/9,600 units every 6 weeks.
[d]9 doses of 395 mg/4,800 units every 3 weeks or 5 doses of 790 mg/9,600 units every 6 weeks.
[e]Patients who experience disease progression or unacceptable toxicity related to KEYTRUDA QLEX with neoadjuvant treatment in combination with chemotherapy should not receive adjuvant single agent KEYTRUDA QLEX.
[f]CPS as determined by an FDA-authorized test.
[g]Refer to the Prescribing Information for the agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Dermatologic Adverse Reactions (*continued*)

Intravenous Pembrolizumab as a Single Agent

- Immune-mediated dermatologic adverse reactions occurred in 1.4% (38/2799) of patients receiving intravenous pembrolizumab, 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 intravenous pembrolizumab in 0.6% (16) of patients. All patients who were withheld reinitiated intravenous pembrolizumab after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Dosing and testing requirements for KEYTRUDA QLEX *(continued)*

Tumor Type	Indication	Biomarker Required	Dose	SC Injection	Duration of Treatment
 **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]	395 mg/4,800 units[b]	2.4 mL in 1 minute every 3 weeks[c]	Treatment should continue until disease progression, unacceptable toxicity, or up to 24 months.
			790 mg/9,600 units[b]	4.8 mL in 2 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]	395 mg/4,800 units[b]	2.4 mL in 1 minute every 3 weeks	
			790 mg/9,600 units[b]	4.8 mL in 2 minutes every 6 weeks	
 **Platinum-resistant ovarian cancer**	**Second-Line or Third-Line Platinum-Resistant Ovarian Carcinoma in Combination with Paclitaxel, With or Without Bevacizumab**	PD-L1 expression (CPS ≥1)[a]	395 mg/4,800 units[b]	2.4 mL in 1 minute every 3 weeks[d]	
			790 mg/9,600 units[b]	4.8 mL in 2 minutes every 6 weeks[d]	

KEYTRUDA QLEX is administered as a subcutaneous (SC) injection into the thigh or abdomen, avoiding the 5-cm area around the navel. KEYTRUDA QLEX must be administered by a healthcare provider.

[a]CPS as determined by an FDA-authorized test.
[b]mg of pembrolizumab/units of berahyaluronidase alfa.
[c]Administer KEYTRUDA QLEX prior to chemotherapy when given on the same day. Refer to Prescribing information for the agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.
[d]Administer KEYTRUDA QLEX prior to paclitaxel with or without bevacizumab when given on the same day. Refer to Prescribing information for the agents administered in combination with KEYTRUDA QLEX for recommended dosing information, as appropriate.

See full Prescribing Information for preparation instructions and dosage modifications for adverse reactions, as well as important dosage and administration information on pages 20-22 of this resource.

SELECTED SAFETY INFORMATION *(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 QLEX 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.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

KEYTRUDA QLEX offers flexible treatment administration

Q3W	Q6W
EVERY 3 WEEKS: 395 mg pembrolizumab/4,800 units berahyaluronidase alfa	EVERY 6 WEEKS: 790 mg pembrolizumab/9,600 units berahyaluronidase alfa
1-minute administration[a]	**2-minute administration[a]**
2.4-mL injection volume	4.8-mL injection volume

[a]Does not account for all aspects of treatment. Actual clinic time may vary.

Q3W = every 3 weeks; Q6W = every 6 weeks.

Patients have the option to switch from KEYTRUDA® (pembrolizumab) to KEYTRUDA QLEX—or KEYTRUDA QLEX to KEYTRUDA—at their next scheduled dose

Two subcutaneous injection-site options

Thigh or abdomen, avoiding the 5-cm area around the navel

KEYTRUDA QLEX can only be administered by a healthcare provider

SELECTED SAFETY INFORMATION *(continued)*

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

Other Immune-Mediated Adverse Reactions (*continued*)

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 (2.8%), 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; *Other*: Myocarditis-Myositis-Myasthenia Gravis (or Myasthenia-Like) Overlap syndrome, reported as the co-occurrence of either two or all three adverse reactions.

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

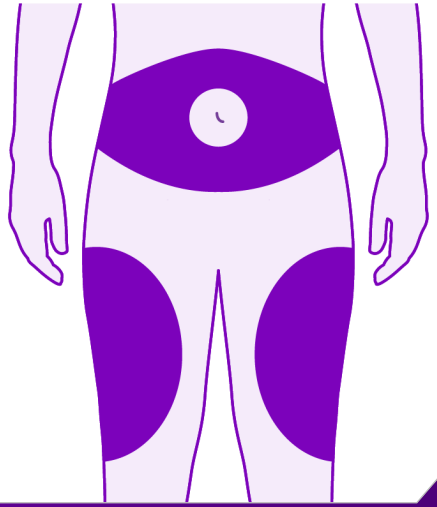
KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Important administration information

Two subcutaneous injection-site options: THIGH or ABDOMEN

KEYTRUDA QLEX must be administered by a healthcare provider

- KEYTRUDA QLEX has different recommended dosage and administration instructions than KEYTRUDA
- Administer KEYTRUDA QLEX as a subcutaneous injection into the thigh or abdomen, avoiding the 5-cm area around the navel
- Inject into healthy skin and never into areas where the skin is red, bruised, tender, or hard
- Ensure the injection site is at least 2.5 cm from the previous injection site
- During treatment with KEYTRUDA QLEX, do not administer other medications for subcutaneous use at the same site as KEYTRUDA QLEX
- Do not administer KEYTRUDA QLEX intravenously



1- or 2-minute subcutaneous administration[a]

EVERY 3 WEEKS

1 minute[a]
one 2.4-mL dose

OR

EVERY 6 WEEKS

2 minutes[a]
one 4.8-mL dose

[a]Does not account for all aspects of treatment. Actual clinic time may vary.

SELECTED SAFETY INFORMATION *(continued)*

Hypersensitivity and Administration-Related Reactions

- KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. In study MK-3475A-D77, hypersensitivity and administration-related systemic reactions occurred in 3.2% (8/251) of patients receiving KEYTRUDA QLEX, including Grade 2 (2.8%). Monitor patients for signs and symptoms of administration-related systemic reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Interrupt injection (if not already fully administered) and resume if symptoms resolve for mild or moderate systemic reactions. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

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.

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pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Preparation of the syringe

1 **Equilibrate the vial**

Remove KEYTRUDA QLEX vial from refrigerated storage (2°C to 8°C [36°F to 46°F]) and allow it to equilibrate to room temperature (20°C to 25°C [68°F to 77°F]) for at least 30 minutes.

- Prior to preparation for administration, if needed, the unpunctured vial may be stored at room temperature for up to 24 hours.

2 **Inspect the vial**

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution is clear to slightly opalescent, colorless to slightly yellow. **Discard the vial if visible particles are observed.**

3 **Withdraw with a transfer needle**

Use a sterile polypropylene or polycarbonate syringe and a stainless steel **transfer needle (18 to 21 gauge)** to withdraw KEYTRUDA QLEX from the vial.

- Q3W (395 mg/4,800 units): withdraw 2.4 mL into the syringe
- Q6W (790 mg/9,600 units): withdraw 4.8 mL into the syringe

4 **Change to an injection needle**

To avoid needle clogging, **change the needle to a 25 to 30 gauge, ½-inch, stainless steel hypodermic injection needle** immediately prior to subcutaneous injection.

5 **Discard any unused portion left in the vial**

IV= intravenous.

KEYTRUDA QLEX offers a fixed dose with no reconstitution or IV line flush needed

SELECTED SAFETY INFORMATION *(continued)*

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of intravenous pembrolizumab 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.

Embryofetal Toxicity

- Based on its mechanism of action, KEYTRUDA QLEX 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 QLEX and advise them to use effective contraception during treatment and for 4 months after the last dose.

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pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Storing the prepared syringe

KEYTRUDA QLEX does not contain a preservative and should be used immediately after withdrawing from the vial. If not used immediately, store the syringe containing KEYTRUDA QLEX with the transfer needle and cap in place:



At room temperature 20°C to 25°C (68°F to 77°F) for up to **8 hours**.

OR



In the refrigerator at 2°C to 8°C (36°F to 46°F) protected from light for up to **96 hours**.
The 96-hour period may include up to 8 hours at room temperature.

Discard if storage time exceeds these limits.

If refrigerated, allow the filled syringe to come to room temperature for at least 30 minutes prior to administration.

Do not freeze.

SELECTED SAFETY INFORMATION *(continued)*

Adverse Reactions

- The most common adverse reactions (≥20%) in patients who received KEYTRUDA QLEX in combination with chemotherapy were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- The safety of KEYTRUDA QLEX for the approved indications is also based on the safety of intravenous pembrolizumab given as a single agent or in combination with other antitumor medicines.
- When intravenous pembrolizumab 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 intravenous pembrolizumab 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 intravenous pembrolizumab 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, decreased appetite, pyrexia, epistaxis, decreased white blood cell count, and stomatitis.
- When intravenous pembrolizumab 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 intravenous pembrolizumab was used in combination with enfortumab vedotin-ejfv, 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.

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KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

Storage of KEYTRUDA QLEX

Storing the vials

- Store vials in the refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light
- Do not shake or freeze vials

KEYTRUDA QLEX



Q3W vial
Yellow cap

395 mg pembrolizumab and 4,800 units berahyaluronidase alfa per 2.4 mL (165 mg/2,000 units per mL)

NDC 0006-3083-01



Q6W vial
Light green cap

790 mg pembrolizumab and 9,600 units berahyaluronidase alfa per 4.8 mL (165 mg/2,000 units per mL)

NDC 0006-5083-01

KEYTRUDA QLEX is a sterile, preservative-free, clear to slightly opalescent, colorless to slightly yellow solution supplied in single-dose vials for subcutaneous administration. Each carton contains one single-dose vial.

Vials shown to scale, not actual size.

NDC = national drug code.

SELECTED SAFETY INFORMATION *(continued)*

Adverse Reactions (*continued*)

- When intravenous pembrolizumab was used in combination with sacituzumab govitecan-hziy, the most common adverse reactions (≥20%) were anemia, neutropenia, diarrhea, nausea, fatigue, alopecia, constipation, rash, vomiting, headache, and abdominal pain.

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 (including 108 pediatric patients aged 12 years to 17 years) were administered intravenous pembrolizumab 2 mg/kg every 3 weeks. The median duration of exposure was 2.1 months (range: 1 day to 25 months).
- The safety and effectiveness of KEYTRUDA QLEX for the treatment of pediatric patients 12 years and older who weigh greater than 40 kg have been established for:
  - Stage IIB, IIC, or III melanoma following complete resection
  - Unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors
  - Recurrent locally advanced or metastatic Merkel cell carcinoma

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SELECTED SAFETY INFORMATION *(continued)*

Pediatric Use *(continued)*

- Use of KEYTRUDA QLEX in pediatric patients for these indications is supported by evidence from adequate and well-controlled studies of intravenous pembrolizumab in adults and additional pharmacokinetic and safety data for intravenous pembrolizumab in pediatric patients 12 years and older. Pembrolizumab exposures in pediatric patients 12 years and older who weigh greater than 40 kg are predicted to be within range of those observed in adults at the same dosage.
- The safety and effectiveness of KEYTRUDA QLEX have not been established in pediatric patients younger than 12 years of age for the treatment of melanoma, MCC, MSI-H or dMMR cancer, and TMB-H cancer.
- The safety and effectiveness of KEYTRUDA QLEX have not been established in pediatric patients for other approved indications shown.
- 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 intravenous pembrolizumab in combination with enfortumab vedotin-ejfv, 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 intravenous pembrolizumab in combination with enfortumab vedotin-ejfv 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 570 patients with MIBC treated with intravenous pembrolizumab in combination with enfortumab vedotin-ejfv, 45% (n=259) were 65-74 years and 22% (n=125) 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 intravenous pembrolizumab in combination with enfortumab vedotin-ejfv experienced a higher incidence of fatal adverse reactions than younger patients. The incidence of fatal adverse reactions was 3.6% in patients younger than 75 and 11% in patients 75 years or older.
- Of 221 adult patients with TNBC who were treated with intravenous pembrolizumab in combination with sacituzumab govitecan-hziy in KEYNOTE-D19, 26% of patients were 65 years and over and 5% were 75 years and older. No overall differences in effectiveness were observed between elderly patients and younger patients. There was a higher rate of serious adverse reactions in patients aged 65 years or older (48%) compared with younger adult patients (34%).

Visit keytrudahcp.com/qlex to learn more about KEYTRUDA QLEX for your appropriate patients

Before prescribing KEYTRUDA QLEX, please read the additional Selected Safety Information throughout and the accompanying Prescribing Information for KEYTRUDA QLEX. The Medication Guide for KEYTRUDA QLEX also is available.

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