KEYTRUDA (SSI)

Selected Safety Information for Keytruda (pembrolizumab)

Indications:

- Melanoma
  - KEYTRUDA (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma.
  - KEYTRUDA as monotherapy is indicated for the adjuvant treatment of patients with Stage III melanoma with involvement of lymph node(s) following complete resection.
- Non-Small Cell Lung Cancer
  - KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
  - KEYTRUDA, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of patients with metastatic squamous NSCLC.
  - KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) ≥ 1%)] as determined by a validated test, with no EGFR or ALK genomic tumor aberrations, and is:
    - stage III where patients are not candidates for surgical resection or definitive chemoradiation, or
    - metastatic
  - KEYTRUDA, as a single agent, is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥1%) as determined by a validated test with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving KEYTRUDA.
- Urothelial Carcinoma
  - KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by a validated test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
  - KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- Classical Hodgkin Lymphoma
  - KEYTRUDA as monotherapy is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV), or who are transplant-ineligible and have failed BV.
- Microsatellite Instability-High or Mismatch Repair Deficient Cancer
  - KEYTRUDA is indicated for the treatment of adult patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
    - solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or
    - colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
- Renal Cell Carcinoma
  - KEYTRUDA, in combination with axitinib, is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

Dosing

Patient Selection for NSCLC or Urothelial Carcinoma: Select patients for treatment with KEYTRUDA as a single agent based on the presence of positive PD-L1 expression in:

- stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation
- metastatic NSCLC
- metastatic urothelial carcinoma

Patient Selection for MSI-H or dMMR Cancer: Select patients for treatment with KEYTRUDA as a single agent based on MSI-H/dMMR status in tumor specimens

- **Melanoma:** The recommended dose of KEYTRUDA in patients with unresectable or metastatic melanoma is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity. The recommended dose of KEYTRUDA for the adjuvant treatment of adult patients with melanoma is 200 mg administered as an intravenous infusion over 30 minutes every 3 weeks until disease recurrence, unacceptable toxicity, or for up to 12 months in patients without disease recurrence.
- **NSCLC:** KEYTRUDA 200 mg should be administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression. When administering KEYTRUDA in combination with chemotherapy, administer KEYTRUDA prior to chemotherapy when given on the same day. Refer to the Prescribing Information for the chemotherapy agents administered in combination with KEYTRUDA for recommended dosing information, as appropriate.
- **Urothelial Carcinoma, Classical Hodgkin Lymphoma, MSI-H or dMMR Cancer:** 200 mg should be administered as an intravenous infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression.
- **Renal Cell Carcinoma:** KEYTRUDA 200 mg should be administered as an intravenous infusion over 30 minutes every 3 weeks in combination of axitinib 5 mg orally twice daily, until disease progression or unacceptable toxicity, or for KEYTRUDA up to 24 months in patients without disease progression. Dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer.
- **Pharmacodynamics:** Based on dose/exposure efficacy and safety relationships, there are no clinically significant differences in efficacy and safety between pembrolizumab doses of 200 mg or 2 mg/kg every 3 weeks in patients with melanoma or NSCLC.
- **Dose modifications:** No dose reductions of KEYTRUDA are recommended. Withhold or discontinue KEYTRUDA to manage adverse reactions as described in full prescribing information

Contraindications:

- None

Precautions:

- **Immune-Mediated Pneumonitis**: KEYTRUDA can cause immune-mediated pneumonitis, including fatal cases. Monitor patients for signs and symptoms of pneumonitis. Evaluate patients with suspected pneumonitis with radiographic imaging and administer corticosteroids (initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper) for Grade 2 or greater pneumonitis. Withhold KEYTRUDA for moderate (Grade 2) pneumonitis, and permanently discontinue KEYTRUDA for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis.
- **Immune-Mediated Colitis:** KEYTRUDA can cause immune-mediated colitis. Monitor patients for signs and symptoms of colitis. Administer corticosteroids (initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper) for Grade 2 or greater colitis. Withhold KEYTRUDA for moderate (Grade 2) or severe (Grade 3) colitis, and permanently discontinue KEYTRUDA for life-threatening (Grade 4) colitis.
- **Immune-Mediated Hepatitis (KEYTRUDA) and Hepatotoxicity (KEYTRUDA in combination with axitinib):** KEYTRUDA can cause immune-mediated hepatitis. Monitor patients for changes in liver function. Administer corticosteroids (initial dose of 0.5 to 1 mg/kg/day [for Grade 2 hepatitis] and 1 to 2 mg/kg/day [for Grade 3 or greater hepatitis] prednisone or equivalent followed by a taper) and, based on severity of liver enzyme elevations, withhold or discontinue KEYTRUDA. KEYTRUDA in combination with axitinib can cause hepatic toxicity with higher than expected frequencies of Grades 3 and 4 ALT and AST elevations compared to KEYTRUDA alone. Monitor liver enzymes before initiation of and periodically throughout treatment. Consider more frequent monitoring of liver enzymes 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.
- **Immune-Mediated Endocrinopathies**:
- ***Adrenal Insufficiency:*** *KEYTRUDA can cause adrenal insufficiency (primary and secondary). Monitor for signs and symptoms of adrenal insufficiency. Administer corticosteroids and hormone replacement as clinically indicated. Withhold KEYTRUDA for moderate (Grade 2) adrenal insufficiency and withhold or discontinue KEYTRUDA for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency.* ***Hypophysitis:*** KEYTRUDA can cause hypophysitis. Monitor for: signs and symptoms of hypophysitis (including hypopituitarism and adrenal insufficiency). Administer corticosteroids and hormone replacement as clinically indicated. Withhold KEYTRUDA for moderate (Grade 2) hypophysitis and withhold or discontinue KEYTRUDA for severe (Grade 3) or life-threatening (Grade 4) hypophysitis. ***Thyroid Disorders****:* KEYTRUDA can cause thyroid disorders, including hyperthyroidism, hypothyroidism and thyroiditis.

Monitor patients for changes in thyroid function (at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation) and for clinical signs and symptoms of thyroid disorders. Administer replacement hormones for hypothyroidism and manage hyperthyroidism with thionamides and beta-blockers as appropriate. Withhold or discontinue KEYTRUDA for severe (Grade 3) or life-threatening (Grade 4) hyperthyroidism. ***Type 1 diabetes mellitus***: KEYTRUDA can cause type 1 diabetes mellitus, including diabetic ketoacidosis, which have been reported in 6 (0.2%) of 2799 patients receiving KEYTRUDA. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Administer insulin for type 1 diabetes, and withhold KEYTRUDA and administer anti-hyperglycemics in patients with severe hyperglycemia

- **Immune-Mediated Nephritis and Renal Dysfunction**: KEYTRUDA can cause immune-mediated nephritis. Monitor patients for changes in renal function. Administer corticosteroids (initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper) for Grade 2 or greater nephritis. Withhold KEYTRUDA for moderate (Grade 2), and permanently discontinue KEYTRUDA for severe (Grade 3) or life-threatening (Grade 4) nephritis.
- **Immune-Mediated Skin Adverse Reactions**: Immune-mediated rashes, including SJS, TEN (some cases with fatal outcome), exfoliative dermatitis, and bullous pemphigoid, can occur. Monitor patients for suspected severe skin reactions and exclude other causes. Based on the severity of the adverse reaction, withhold or permanently discontinue KEYTRUDA and administer corticosteroids. For signs or symptoms of SJS or TEN, withhold KEYTRUDA and refer the patient for specialized care for assessment and treatment. If SJS or TEN is confirmed, permanently discontinue KEYTRUDA.
- **Other Immune-Mediated Adverse Reactions**: Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue in patients receiving KEYTRUDA. While immune-mediated adverse reactions usually occur during treatment with PD-1/PD-L1 blocking antibodies, they may occur after discontinuation of treatment. For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm etiology or exclude other causes. Based on the severity of the adverse reaction, withhold KEYTRUDA and administer corticosteroids. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Based on limited data from clinical studies in patients whose immune-related adverse reactions could not be controlled with corticosteroid use, administration of other systemic immunosuppressants can be considered. Resume KEYTRUDA when the immune-mediated adverse reaction remains at Grade 1 or less following corticosteroid taper. Permanently discontinue KEYTRUDA for any Grade 3 immune-mediated adverse reaction that recurs and for any life-threatening immune-mediated adverse reaction. The following clinically significant, immune-mediated adverse reactions occurred in less than 1% (unless otherwise indicated) of 2799 patients treated with KEYTRUDA: arthritis (1.5%), uveitis, myositis, Guillain-Barré syndrome, myasthenia gravis, vasculitis, pancreatitis, hemolytic anemia, sarcoidosis, and encephalitis. In addition, myelitis and myocarditis were reported in other clinical trials, including cHL, and post-marketing use. Solid organ transplant rejection has been reported in the post-marketing setting in patients treated with KEYTRUDA. Treatment with KEYTRUDA may increase the risk of rejection in solid organ transplant recipients. Consider the benefit of treatment with KEYTRUDA versus the risk of possible organ rejection in these patients.
- **Infusion-Related Reactions**: KEYTRUDA can cause severe or life-threatening infusion-related reactions, including hypersensitivity and anaphylaxis, which have been reported in 6 (0.2%) of 2799 patients receiving KEYTRUDA. Monitor patients for signs and symptoms of infusion-related reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. For severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions, stop infusion and permanently discontinue KEYTRUDA.
- **Complications of Allogeneic HSCT:** ***Allogeneic HSCT after treatment with KEYTRUDA*** Immune-mediated complications, including fatal events, occurred in patients who underwent allogeneic hematopoietic stem cell transplantation (HSCT) after being treated with KEYTRUDA. Of 23 patients with cHL who proceeded to allogeneic HSCT after treatment with KEYTRUDA on any trial, 6 patients (26%) developed graft-versus-host-disease (GVHD), one of which was fatal, and 2 patients (9%) developed severe hepatic veno-occlusive disease (VOD) after reduced-intensity conditioning, one of which was fatal. Cases of fatal hyperacute GVHD after allogeneic HSCT have also been reported in patients with lymphoma who received a PD-1 receptor blocking antibody before transplantation. These complications may occur despite intervening therapy between PD-1 blockade and allogeneic HSCT. Follow patients closely for early evidence of transplant-related complications such as hyperacute GVHD, severe (Grade 3 to 4) acute GVHD, steroid-requiring febrile syndrome, hepatic VOD, and other immune mediated adverse reactions, and intervene promptly. ***Allogeneic HSCT prior to treatment with KEYTRUDA***: In patients with a history of allogeneic HSCT, acute GVHD, including fatal GVHD, has been reported after treatment with KEYTRUDA. Patients who experienced GVHD after their transplant procedure may be at increased risk for GVHD after treatment with KEYTRUDA. Consider the benefit of treatment with KEYTRUDA versus the risk of possible GVHD in patients with a history of allogeneic HSCT.
- **Increased Mortality in Patients with Multiple Myeloma when KEYTRUDA is Added to a Thalidomide Analogue and Dexamethasone**: In two randomized clinical trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone, a use for which no PD-1 or PD-L1 blocking antibody is indicated, resulted

in increased mortality. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

- **Embryo-Fetal Toxicity**: Based on its mechanism of action, KEYTRUDA can cause fetal harm when administered to a pregnant woman. Animal models link the PD-1/PD-L1 signaling pathway with maintenance of pregnancy through induction of maternal immune tolerance to fetal tissue. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with KEYTRUDA and for 4 months after the last dose.

For detailed precautions and respective incidence rates per indications, please consult the full prescribing information

Adverse Events:

Most common adverse reactions (reported in ≥20% of patients) when KEYTRUDA was used as a single agent were fatigue, musculoskeletal pain, decreased appetite, pruritus, diarrhea, nausea, rash, pyrexia, cough, dyspnea, constipation, pain, and abdominal pain; when KEYTRUDA was used in combination with chemotherapy were fatigue/asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, dyspnea, pyrexia , alopecia, peripheral neuropathy, mucosal inflammation, and stomatitis; when KEYTRUDA in combination with axitinib were diarrhea, fatigue/asthenia, hypertension, hepatotoxicity, hypothyroidism, decreased appetite, palmar-plantar erythrodysesthesia, nausea, stomatitis/mucosal inflammation, dysphonia, rash, cough, and constipation.

- Immune-mediated pneumonitis
- Immune-mediated colitis
- Immune-mediated hepatitis (KEYTRUDA) and hepatotoxicity (KEYTRUDA in combination with axitinib)
- Immune-mediated endocrinopathies
- Immune-mediated nephritis and renal dysfunction
- Immune-mediated skin adverse reactions
- Other immune-mediated adverse reactions
- Infusion-related reactions

Melanoma

- For **Ipilimumab-Naive Melanoma** patients receiving KEYTRUDA 2 mg/kg or 10 mg/kg every 3 weeks, selected adverse reactions (≥10%): Fatigue, Rash, Vitiligo, Arthralgia, Back pain, Cough, Dyspnea, Decreased appetite, Headache, Diarrhea, Nausea, Pruritus. Selected laboratory abnormalities (≥20%): Hyperglycemia, Hypertriglyceridemia, Hyponatremia, Increased AST, Hypercholesterolemia, Anemia, Lymphopenia, Increased hypoalbuminemia, Increased ALT, Increased alkaline phosphatase.
- For **Ipilimumab-Refractory Melanoma** patients receiving KEYTRUDA 2 mg/kg or 10 mg/kg every 3 weeks, selected adverse reactions (≥10%): Pyrexia, Asthenia, Pruritus, Rash, Constipation, Diarrhea, Abdominal pain, Cough, Arthralgia, Fatigue, Nausea, Decreased appetite, Vomiting. Selected laboratory abnormalities (≥20%): Hyperglycemia, Hypoalbuminemia, Hyponatremia, Hypertriglyceridemia, Increased alkaline phosphatase, Increased AST & ALT, Bicarbonate decreased, Hypocalcemia, Anemia, Lymphopenia.
- For **Adjuvant Treatment of Resected Melanoma**: Adverse reactions leading to permanent discontinuation occurred in 14% of patients receiving KEYTRUDA; the most common (≥1%) were pneumonitis (1.4%), colitis (1.2%), and diarrhea (1%). Adverse reactions leading to interruption of KEYTRUDA occurred in 19% of patients; the most common (≥1%) were diarrhea (2.4%), pneumonitis (2%), increased ALT (1.4%), arthralgia (1.4%), increased AST (1.4%), dyspnea (1%), and fatigue (1%).

NSCLC

- **First-line treatment of metastatic nonsquamous NSCLC with pemetrexed and platinum chemotherapy**: The most common adverse reactions resulting in permanent discontinuation of KEYTRUDA were pneumonitis (3%) and acute kidney injury (2%). Adverse reactions leading to the interruption of KEYTRUDA occurred in 53% of patients; the most common adverse reactions or laboratory abnormalities leading to interruption of KEYTRUDA (≥2%) were neutropenia (13%), asthenia/fatigue (7%), anemia (7%), thrombocytopenia (5%), diarrhea (4%), pneumonia (4%), increased blood creatinine (3%), dyspnea (2%), febrile neutropenia (2%), upper respiratory tract infection (2%), increased ALT (2%), and pyrexia (2%).
- **First-line treatment of metastatic squamous NSCLC with carboplatin and either paclitaxel or paclitaxel protein-bound chemotherapy:** KEYTRUDA was discontinued for adverse reactions in 15% of patients, with no single type of adverse reaction accounting for the majority. Adverse reactions leading to interruption of KEYTRUDA occurred in 43% of patients; the most common (≥2%) were thrombocytopenia (20%), neutropenia (11%), anemia (6%), asthenia (2%), and

diarrhea (2%). The most frequent (≥2%) serious adverse reactions were febrile neutropenia (6%), pneumonia (6%), and urinary tract infection (3%).

- **Previously Untreated NSCLC:** KEYTRUDA was discontinued for adverse reactions in 19% of patients. The most common adverse reactions resulting in permanent discontinuation of KEYTRUDA were pneumonitis (3.0%), death due to unknown cause (1.6%), and pneumonia (1.4%). Adverse reactions leading to interruption of KEYTRUDA occurred in 33% of patients; the most common adverse reactions or laboratory abnormalities leading to interruption of KEYTRUDA (≥2%) were pneumonitis (3.1%), pneumonia (3.0%), hypothyroidism (2.2%), and increased ALT (2.0%). The most frequent (≥2%) serious adverse reactions were pneumonia (7%), pneumonitis (3.9%), pulmonary embolism (2.4%), and pleural effusion (2.2%)
- **Previously Treated Metastatic NSCLC:** the adverse reaction profile was similar for the 2 mg/kg and 10 mg/kg dose, therefore summary safety results are provided in a pooled analysis (n=682). Treatment was discontinued for adverse reactions in 8% of patients receiving KEYTRUDA. The most common adverse events resulting in permanent discontinuation of KEYTRUDA was pneumonitis (1.8%). Adverse reactions leading to interruption of KEYTRUDA occurred in 23% of patients; the most common (≥1%) were diarrhea (1%), fatigue (1.3%), pneumonia (1%), liver enzyme elevation (1.2%), decreased appetite (1.3%), and pneumonitis (1%).

Urothelial Carcinoma

- **Cisplatin Ineligible patients with Urothelial Carcinoma** receiving KEYTRUDA 200 mg every 3 weeks, selected adverse reactions (≥10%): Fatigue, Pyrexia, Weight loss, Musculoskeletal pain, Arthralgia, Decreased appetite, Hyponatremia, Constipation, Diarrhea, Nausea, Abdominal pain, Elevated LFTs, Vomiting, Rash, Pruritus, Edema peripheral, Urinary tract infection, Anemia, Cough, Dyspnea, Increased Blood creatinine and Hematuria.
- **Previously Treated Urothelial Carcinoma** patients receiving KEYTRUDA 200 mg every 3 weeks, selected adverse reactions (≥10%): Fatigue, Pyrexia, Musculoskeletal pain, Pruritus, Rash, Nausea, Constipation, Diarrhea, Vomiting, Abdominal pain, Decreased appetite, Urinary tract infection, Cough, Dyspnea and Hematuria. Selected laboratory abnormalities (≥20%): Hyperglycemia, Anemia, Lymphopenia, Hypoalbuminemia, Hyponatremia, Increased alkaline phosphatase, Increased creatinine, Hypophosphatemia, Increased AST, Hyperkalemia and Hypocalcemia.

Classical Hodgkin Lymphoma

- For patients receiving KEYTRUDA 200 mg every 3 weeks, selected adverse reactions (≥10%): Fatigue, Pyrexia, Cough, Dyspnea, Musculoskeletal pain, Arthralgia, Diarrhea, Vomiting, Nausea, Rash, Pruritus, Hypothyroidism, Upper respiratory tract infection, Headache, Peripheral neuropathy. Selected laboratory abnormalities (≥15%): Hypertransaminasemia, Increased alkaline phosphatase, Increased creatinine, Anemia, Thrombocytopenia and Neutropenia.

Renal Cell Carcinoma

- For patients receiving KEYTRUDA 200 mg every 3 weeks and axitinib 5 mg orally twice daily, the most common adverse reactions (≥20%): diarrhea, fatigue/asthenia, hypertension, hypothyroidism, decreased appetite, hepatotoxicity, palmar-plantar erythrodysesthesia, nausea, stomatitis/mucosal inflammation, dysphonia, rash, cough, and constipation. Selected laboratory abnormalities (≥20%): Hyperglycemia, Increased ALT, Increased AST, Increased creatinine, Hyponatremia, Hyperkalemia, Hypoalbuminemia, Hypercalcemia, Hypophosphatemia, Increased alkaline phosphatase, Hypocalcemia, Increased Blood bilirubin, Activated partial thromboplastin time prolonged, Lymphopenia, Anemia and Thrombocytopenia

As with all therapeutic proteins, there is the potential for immunogenicity. For detailed adverse events, please consult the full prescribing information.

<u>Use in Specific Populations:</u>

- Pregnancy
  - Based on its mechanism of action, KEYTRUDA can cause fetal harm when administered to a pregnant woman. There are no available human data informing the risk of embryo-fetal toxicity. In animal models, the PD-1/PD-L1 signaling pathway is important in the maintenance of pregnancy through induction of maternal immune tolerance to fetal tissue. Human IgG4 (immunoglobulins) are known to cross the placenta; therefore, pembrolizumab has the potential to be transmitted from the mother to the developing fetus. Advise pregnant women of the potential risk to a fetus.
- Lactation
  - There are no data on the presence of pembrolizumab in either animal or human milk or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed

children, advise women not to breastfeed during treatment with KEYTRUDA and for 4 months after the final dose.

- Females and Males of Reproductive Potential
  - Pregnancy Testing: Verify pregnancy status in females of reproductive potential prior to initiating KEYTRUDA.
  - Contraception: KEYTRUDA can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with KEYTRUDA and for at least 4 months following the final dose.
- Pediatric Use
  - Safety and effectiveness of KEYTRUDA have not been established in pediatric patients.
- Geriatric Use
  - Of the 3145 patients who were treated with KEYTRUDA in clinical studies, 43% were 65 years and over and 12% were 75 years and over. No overall differences in safety or effectiveness were observed between elderly patients and younger patients.

Before prescribing, please consult the full prescribing information