TEVIMBRA®
(tislelizumab-jsgr) Injection, for intravenous use 10 mg/mL

Dosing and Administration

UPPER GI

Most flexible set of dosing regimens across indications, providing convenient treatment planning[1-3]

Synchronize TEVIMBRA with your preferred chemotherapy

Q2W	Q3W
150 mg once every 2 weeks	200 mg once every 3 weeks

Offer convenient scheduling with fewer infusion visits for patients

Q4W	Q6W
300 mg once every 4 weeks	400 mg once every 6 weeks

Preparing and administering TEVIMBRA[1]

1. **Withdraw** from the vials the required amount of TEVIMBRA that aligns with your chosen dosing regimen.

2. **Transfer** the solution into an IV infusion bag containing 0.9% Sodium Chloride Injection, USP, to prepare an infusion with a final concentration of 2 mg/mL to 5 mg/mL.

3. **Mix** the diluted solution by gentle inversion to avoid foaming or excessive shearing of the solution. DO NOT SHAKE.

4. **Store** the diluted solution in a refrigerator at 2 °C to 8 °C (36 °F to 46 °F) for up to 10 days (240 hours), including preparation and infusion duration, or at room temperature (20 °C to 25 °C, or 68 °F to 77 °F) for no more than 4 hours, including preparation and infusion duration. Allow the refrigerated solution to come to room temperature prior to administration. Discard after 10 days (240 hours). Protect the diluted solution from light during storage. DO NOT FREEZE.

5. **Administer** by IV infusion through an IV line with a sterile, nonpyrogenic, low-protein–binding, 0.2- or 0.22-micron in-line or add-on filter.
   - **For 150-mg and 200-mg doses,** administer the initial infusion over 60 minutes. If tolerated, all subsequent infusions may be administered over 30 minutes
   - **For 300-mg doses,** administer the initial infusion over 90 minutes. If tolerated, administer the second infusion over 60 minutes. If the second infusion is tolerated, administer subsequent infusions over 30 minutes
   - **For 400-mg doses,** administer the initial infusion over 120 minutes. If tolerated, administer the second infusion over 60 minutes. If the second infusion is tolerated, administer subsequent infusions over 30 minutes

Important reminders

- TEVIMBRA should be inspected visually for particulate matter and discoloration prior to administration
- Do not coadminister other drugs through the same infusion line
- Do not administer TEVIMBRA as an intravenous push or single bolus injection
- The intravenous line must be flushed at the end of the infusion
- TEVIMBRA is for single use only. Discard any unused portion left in the vial

Learn more at TEVIMBRAhcp.com

INDICATIONS

TEVIMBRA is a programmed death receptor-1 (PD-1)-blocking antibody indicated for:

Esophageal Cancer

- in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
- as a single-agent, for the treatment of adults with unresectable or metastatic ESCC after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Gastric Cancer

- in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Severe and Fatal Immune-Mediated Adverse Reactions

TEVIMBRA is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or PD-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. Immune-mediated adverse reactions can occur at any time after starting treatment with a PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated reactions.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. 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.

Please see Important Safety Information on the following page and full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

Withhold or permanently discontinue TEVIMBRA depending on severity. In general, if TEVIMBRA 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 immune-mediated adverse reactions are not controlled with corticosteroids.

Immune-Mediated Pneumonitis

TEVIMBRA can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1 blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 4.7% (113/2390) of patients receiving TEVIMBRA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (1.4%) and Grade 2 (1.9%) adverse reactions. Pneumonitis led to permanent discontinuation of TEVIMBRA in 44 (1.8%) patients and withholding of TEVIMBRA in 40 (1.7%) patients.

Eighty-one (71.7%) of the 113 patients received systemic corticosteroids. Seventy-four (65.5%) of the 113 patients received high-dose systemic corticosteroids. Immune-mediated pneumonitis resolved in 48.7% of the 113 patients. Of the 40 patients in whom TEVIMBRA was withheld for pneumonitis, 26 (65%) reinitiated TEVIMBRA after symptom improvement; of these, 5 (19%) patients had recurrence of pneumonitis.

Immune-Mediated Colitis

TEVIMBRA can cause immune-mediated colitis, which can be fatal. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1 blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 0.8% (19/2390) of patients receiving TEVIMBRA, including Grade 3 (0.3%) and Grade 2 (0.4%) adverse reactions. Colitis led to permanent discontinuation of TEVIMBRA in 5 (0.2%) patients and withholding of TEVIMBRA in 10 (0.4%) patients. Seventeen (89.5%) of the 19 patients received systemic corticosteroids. Twelve (63.2%) of the 19 patients received high-dose systemic corticosteroids. Two (10.5%) of the 19 patients received immunosuppressive treatment. Immune-mediated colitis resolved in 89.5% of the 19 patients. Of the 10 patients in whom TEVIMBRA was withheld for colitis, 9 (90%) reinitiated TEVIMBRA after symptom improvement; of these, 2 (22%) patients had recurrence of colitis.

Immune-Mediated Hepatitis

TEVIMBRA can cause immune-mediated hepatitis, which can be fatal.

Immune-mediated hepatitis occurred in 1.3% (30/2390) of patients receiving TEVIMBRA, including Grade 4 (0.3%), Grade 3 (0.6%), and Grade 2 (0.3%) adverse reactions. Immune-mediated hepatitis led to permanent discontinuation in 6 (0.3%) patients and withholding of TEVIMBRA in 19 (0.8%) patients. Twenty-five (83.3%) of the 30 patients received systemic corticosteroids. Twenty-four (80%) of the 30 patients received high-dose systemic corticosteroids. Two (6.7%) of the 30 patients received immunosuppressive treatment. Immune-mediated hepatitis resolved in 66.7% of the 30 patients. Of the 19 patients in whom TEVIMBRA was withheld for hepatitis, 7 (37%) reinitiated TEVIMBRA after symptom improvement; of these, 1 (14%) patient had recurrence of hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

TEVIMBRA can cause immune-mediated adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold TEVIMBRA depending on severity.

Immune-mediated adrenal insufficiency occurred in 0.5% (12/2390) of patients receiving TEVIMBRA, including Grade 4 (0.04%), Grade 3 (0.2%), and Grade 2 (0.3%) adverse reactions. Adrenal insufficiency did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 10 (0.4%) patients. All 12 patients received systemic corticosteroids. Three (25%) of the 12 patients received high-dose systemic corticosteroids. Adrenal insufficiency resolved in 25% of the 12 patients. Of the 10 patients in whom TEVIMBRA was withheld for adrenal insufficiency, 8 (80%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of adrenal insufficiency.

Hypophysitis

TEVIMBRA 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 clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Hypophysitis/hypopituitarism occurred in 0.3% (6/2390) of patients receiving TEVIMBRA; all were Grade 2 (0.3%). Hypophysitis did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 1 (0.04%) patient. Five (83.3%) of the 6 patients received systemic corticosteroids. One (17%) of the 6 patients received high-dose systemic corticosteroids. Hypophysitis/hypopituitarism resolved in 17% of the 6 patients. For the 1 patient where TEVIMBRA was withheld for hypophysitis/hypopituitarism, there was no recurrence of hypophysitis/hypopituitarism.

Thyroid Disorders

TEVIMBRA can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Thyroiditis: Immune-mediated thyroiditis occurred in 1% (25/2390) of patients receiving TEVIMBRA, including Grade 2 (0.5%) adverse reactions. Thyroiditis did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 5 (0.2%) patients. Two (8%) of the 25 patients received systemic corticosteroids. Thyroiditis resolved in 36% of the 25 patients. All 5 patients in whom TEVIMBRA was withheld for thyroiditis reinitiated TEVIMBRA after symptom improvement; of these, 1 (20%) patient had recurrence of thyroiditis.

Hyperthyroidism: Immune-mediated hyperthyroidism occurred in 4.9% (118/2390) of patients receiving TEVIMBRA, including Grade 3 (0.04%) and Grade 2 (0.9%) adverse reactions. Hyperthyroidism led to the permanent discontinuation of TEVIMBRA in 1 (0.04%) patient and withholding of TEVIMBRA in 7 (0.3%) patients. Three (2.5%) of the 118 patients received systemic corticosteroids. Hyperthyroidism resolved in 76.3% of the 118 patients. Of the 7 patients in whom TEVIMBRA was withheld for hyperthyroidism, 5 (71.4%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of hyperthyroidism.

Hypothyroidism: Immune-mediated hypothyroidism occurred in 12.5% (299/2390) of patients receiving TEVIMBRA, including Grade 4 (0.04%), Grade 3 (0.04%), and Grade 2 (6.7%) adverse reactions. TEVIMBRA was permanently discontinued in 2 (0.1%) patients and treatment was withheld in 12 (0.5%) patients. Two (0.7%) of the 299 patients received systemic corticosteroids. One hundred ninety-five patients received hormone replacement therapy. Hypothyroidism resolved in 34.4% of the 299 patients. The majority (83.6%) of patients with hypothyroidism required long-term thyroid hormone replacement. Of the 12 patients in whom TEVIMBRA was withheld for hypothyroidism, 11 (91.7%) reinitiated TEVIMBRA after symptom improvement; of these, 2 (18.2%) patients had recurrence of hypothyroidism.

Type 1 Diabetes Mellitus, which can present with Diabetic Ketoacidosis

Diabetes mellitus has been reported with PD-1/PD-L1 blocking antibodies. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Diabetes mellitus occurred in 0.7% (16/2390) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) adverse reactions. TEVIMBRA was permanently discontinued in 4 (0.2%) patients, and TEVIMBRA treatment was withheld in 4 (0.2%) patients. Fourteen of the 16 patients received insulin therapy for diabetes mellitus. Diabetes mellitus resolved in 12.5% of the 16 patients. Of the 4 patients in whom TEVIMBRA was withheld for diabetes mellitus, 1 (25%) patient reinitiated TEVIMBRA after symptom improvement.

Immune-Mediated Nephritis with Renal Dysfunction

TEVIMBRA can cause immune-mediated nephritis, which can be fatal.

Immune-mediated nephritis with renal dysfunction occurred in 0.2% (5/2390) of patients receiving TEVIMBRA, including Grade 3 (0.04%) and Grade 2 (0.1%) adverse reactions. TEVIMBRA was permanently discontinued in 1 (0.04%) patient and treatment was withheld in 3 (0.1%) patients. Three (60%) out of 5 patients received systemic corticosteroids. Three (60%) of the 5 patients received high-dose systemic corticosteroids. Nephritis with renal dysfunction resolved in 40% of the 5 patients. Of the 3 patients in whom TEVIMBRA was withheld for nephritis, 2 (66.7%) reinitiated TEVIMBRA after symptom improvement and no patients had recurrence of nephritis.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

Immune-Mediated Dermatologic Adverse Reactions

TEVIMBRA can cause immune-mediated rash or dermatitis. Cases of severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported, some with fatal outcome. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue TEVIMBRA depending on severity.

Immune-mediated dermatologic adverse reactions occurred in 13% (311/2390) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (1.1%), and Grade 2 (3.4%) adverse reactions. Stevens-Johnson syndrome occurred in 1 (0.04%) patient. Dermatologic adverse reactions led to permanent discontinuation of TEVIMBRA in 3 (0.1%) patients and withholding of TEVIMBRA in 30 (1.3%) patients. Forty-four (14.1%) of the 311 patients received systemic corticosteroids. Nineteen (6.1%) of the 311 patients received high-dose systemic corticosteroids. Immune-mediated skin reactions resolved in 66.9% of the 311 patients. Of the 30 patients in whom TEVIMBRA was withheld for dermatologic adverse reactions, 26 (86.7%) reinitiated TEVIMBRA after symptom improvement; of these, 3 (12%) patients had recurrence of immune-mediated dermatologic adverse reactions.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of less than 1% in 2390 patients who received TEVIMBRA or were reported with the use of other PD-1/PD-L1 blocking antibodies. 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-Barre syndrome, nerve paresis, autoimmune neuropathy.

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis, stomatitis.

Musculoskeletal and Connective Tissue: Myositis/polymyositis/dermatomyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica.

Endocrine: Hypoparathyroidism.

Other (Hematologic/Immune): Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

TEVIMBRA can cause severe or life-threatening infusion-related reactions. Infusion-related reactions occurred in 5% (99/1972) patients receiving TEVIMBRA, including Grade 3 or higher (0.2%) reactions. Monitor patients for signs and symptoms of infusion-related reactions.

Slow the rate of infusion for mild (Grade 1) and interrupt the infusion for moderate (Grade 2) infusion-related reactions. For severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions, stop infusion and permanently discontinue TEVIMBRA.

Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, 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 PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action, TEVIMBRA can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TEVIMBRA and for 4 months after the last dose.

ADVERSE REACTIONS

First-line Treatment of Unresectable Advanced or Metastatic Esophageal Carcinoma (ESCC)

Permanent discontinuation of TEVIMBRA due to adverse reactions occurred in 13% of patients. The adverse reaction which resulted in discontinuation in ≥2% of patients was pneumonitis (2.2%).

Dosage interruptions of TEVIMBRA due to adverse reactions occurred in 52% of patients. Adverse reactions which required dosage interruption in ≥2% of patients were neutrophil count decreased (7%), fatigue (6%), pneumonia (6%), anemia (4.3%), neutropenia (4.3%), white blood cell count decreased (4.3%), rash (3.7%), dysphagia (2.8%), platelet count decreased (2.8%), pyrexia (2.8%), and diarrhea (2.2%).

The most common (≥20%) adverse reactions, including laboratory abnormalities were decreased neutrophil count, decreased sodium, increased glucose, anemia, fatigue, decreased appetite, increased AST, decreased potassium, increased serum creatinine, decreased calcium, increased ALT, diarrhea, stomatitis, and vomiting.

Previously Treated Unresectable Advanced or Metastatic ESCC

Permanent discontinuation of TEVIMBRA due to an adverse reaction occurred in 19% of patients. Adverse reactions which resulted in permanent discontinuation in ≥1% of patients were hemorrhage, pneumonitis (including pneumonitis and immune-mediated pneumonitis), and pneumonia.

Dosage interruptions of TEVIMBRA due to an adverse reaction occurred in 23% of patients. Adverse reactions which required dosage interruptions in ≥2% of patients were pneumonia, pneumonitis, and fatigue.

The most common (≥20%) adverse reactions, including laboratory abnormalities, were increased glucose, decreased hemoglobin, decreased lymphocytes, decreased sodium, decreased albumin, increased alkaline phosphatase, anemia, fatigue, increased AST, musculoskeletal pain, decreased weight, increased ALT, and cough.

Treatment of Previously Untreated Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (G/GEJ)

Permanent discontinuation of TEVIMBRA due to an adverse drug reaction occurred in 16% of patients. Adverse drug reactions which resulted in permanent discontinuation in ≥1% of patients were death, fatigue, and pneumonitis.

Dosage interruption of TEVIMBRA in the TEVIMBRA plus chemotherapy arm due to an adverse drug reaction occurred in 49% of patients. Adverse drug reactions which required dosage modifications in ≥2% of patients were, platelet count decreased (12%), neutrophil count decreased (10%), neutropenia (6%), white blood cell count decreased (6%), increased AST (4.8%), increased ALT (3.8%), increased blood bilirubin (3%), COVID-19 (3%), thrombocytopenia (2.8%), leukopenia (2.6%), pneumonitis (2.2%), and pneumonia (2%).

The most common (≥20%) adverse reactions, including laboratory abnormalities, for TEVIMBRA in combination with chemotherapy were nausea, fatigue, decreased appetite, anemia, peripheral sensory neuropathy, vomiting, decreased platelet count, decreased neutrophil count, increased aspartate aminotransferase, diarrhea, abdominal pain, increased alanine aminotransferase, decreased white blood cell count, decreased weight, and pyrexia.

Please see full Prescribing Information for TEVIMBRA.

GI, gastrointestinal; IV, intravenous; Q2W, every 2 weeks; Q3W, every 3 weeks; Q4W, every 4 weeks; Q6W, every 6 weeks.

References: 1. TEVIMBRA. Prescribing Information. BeOne Medicines USA, Inc.; 2025. **2.** Keytruda. Prescribing Information. Merck & Co., Inc.; 2025. **3.** Opdivo. Prescribing Information. Bristol-Myers Squibb Company; 2025.

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