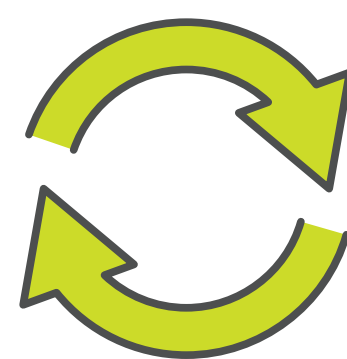


Dosing and Administration



TEVIMBRA offers the most flexible set of dosing schedules of PD-1 inhibitors across its approved indications¹⁻³



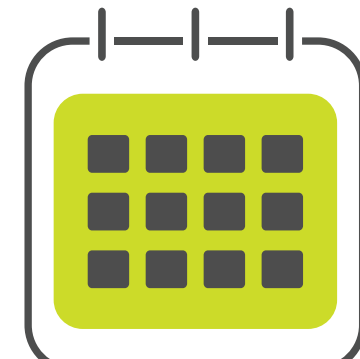
Synchronize TEVIMBRA with your preferred chemotherapy*

Q2W

150 mg once
every 2 weeks

Q3W

200 mg once
every 3 weeks



Offer convenient scheduling with fewer infusion visits for patients

Q4W

300 mg once
every 4 weeks

Q6W

400 mg once
every 6 weeks

Preparing and administering TEVIMBRA¹



1. Withdraw from the vial 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 if not used immediately, in either 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 reminders¹

- 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 IV push or single bolus injection
- The IV line must be flushed at the end of the infusion
- TEVIMBRA is for single use only. Discard any unused portion left in the vial

Combining TEVIMBRA with zanidatamab-hrii and chemotherapy^{1,4,5}

- For patients with 1L HER2+ unresectable locally advanced or metastatic GEA, **TEVIMBRA dosing can be synchronized with zanidatamab-hrii and chemotherapy on a Q2W or Q3W schedule**
- When administering TEVIMBRA in combination with zanidatamab-hrii and chemotherapy: zanidatamab-hrii should be administered first, followed by TEVIMBRA, and then chemotherapy. For additional dosing and safety information, please refer to the zanidatamab-hrii Prescribing Information, including Boxed Warning
- Patients in the zanidatamab-hrii-containing arms of the HERIZON-GEA-01 trial received mandatory prophylaxis for diarrhea (loperamide administered orally at 4 mg twice daily for the first 7 days of Cycle 1) and infusion-related reactions (glucocorticoids, antihistamines, and acetaminophen administered 30 to 60 minutes before infusion). Refer to the zanidatamab-hrii Prescribing Information for additional dosing information
- The overall management of certain ARs may require treatment interruption or treatment discontinuation, depending on severity

*Fluoropyrimidine- and platinum-containing chemotherapy for 1L HER2+ GEA; fluoropyrimidine- and platinum-containing chemotherapy for 1L HER2- GC/GEJC; platinum-containing chemotherapy for 1L ESCC.

Learn more at [TEVIMBRAhcp.com](https://www.tevimbrahcp.com)

INDICATIONS

TEVIMBRA is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adults with:

- **Gastric, Gastroesophageal Junction, or Esophageal Adenocarcinoma:** In combination with zanidatamab-hrii and fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment of HER2-positive (IHC 3+ or IHC 2+/ISH+) unresectable locally advanced or metastatic gastric, gastroesophageal junction, or esophageal adenocarcinoma.
- **Esophageal Cancer:** In combination with platinum-containing chemotherapy for first-line treatment of unresectable or metastatic esophageal squamous cell carcinoma (ESCC) expressing PD-L1 (≥1).
- **Gastric Cancer:** In combination with fluoropyrimidine- and platinum-containing chemotherapy for first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1).

IMPORTANT SAFETY INFORMATION WARNINGS & PRECAUTIONS

- **Immune-Mediated Adverse Reactions (IMARs):** TEVIMBRA can cause immune-mediated adverse reactions, which may be severe or fatal and can occur in any organ system or tissue. Early identification and management of IMARs are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. IMARs may occur at any time during or after treatment. Monitor for signs and symptoms of IMARs. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. For suspected IMARs, initiate appropriate workup to exclude alternative etiologies. Withhold or permanently discontinue TEVIMBRA based on severity and administer systemic corticosteroids or other immunosuppressants as clinically indicated. The IMARs listed were observed in clinical studies of TEVIMBRA (n=2390) and may not include all possible severe and fatal IMARs.
 - **Pneumonitis:** TEVIMBRA can cause immune-mediated pneumonitis, which can be fatal. Immune-mediated pneumonitis occurred in 4.7% of patients, including Grade 3-4 reactions in 1.7% and fatal events in 0.1%.
 - **Colitis:** TEVIMBRA can cause immune-mediated colitis, which can be fatal. Immune-mediated colitis occurred in 0.8% of patients, including Grade 3 reactions in 0.3%.
 - **Hepatitis:** TEVIMBRA can cause immune-mediated hepatitis, which can be fatal. Immune-mediated hepatitis occurred in 1.3% of patients, including Grade 3-4 reactions in 0.9%.

Please see additional Important Safety Information on the following page and full Prescribing Information for preparation and administration instructions and dosage modifications for adverse reactions.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS & PRECAUTIONS (cont'd)

- **Immune-Mediated Adverse Reactions (IMARs):** (cont'd)
 - **Endocrinopathies:** TEVIMBRA can cause immune-mediated endocrinopathies, including adrenal insufficiency, hypophysitis/hypopituitarism, thyroid disorders, and type 1 diabetes mellitus. Reported rates included adrenal insufficiency (0.5%; Grade 3-4: 0.24%), hypophysitis/hypopituitarism (0.3%; all Grade 2), thyroiditis (1.0%; Grade 2: 0.5%), hyperthyroidism (4.9%; Grade 3: 0.04%), hypothyroidism (12.5%; Grade 3-4: 0.08%), and diabetes mellitus (0.7%; Grade 3-4: 0.4%).
 - **Nephritis with Renal Dysfunction:** TEVIMBRA can cause immune-mediated nephritis with renal dysfunction, which can be fatal. Immune-mediated nephritis with renal dysfunction occurred in 0.2% of patients, including Grade 3 reactions in 0.04%.
 - **Dermatologic Adverse Reactions:** TEVIMBRA can cause immune-mediated rash or dermatitis, including severe cutaneous adverse reactions. Immune-mediated dermatologic adverse reactions occurred in 13% of patients, including Grade 3-4 reactions in 1.2%; Stevens-Johnson syndrome occurred in 0.04% of patients.
 - **Other Immune-Mediated Adverse Reactions:** Other clinically significant immune-mediated adverse reactions occurred in <1% of patients and may involve cardiac/vascular, neurologic, ocular, gastrointestinal, musculoskeletal/connective tissue, endocrine, and hematologic/immune systems (including solid organ transplant rejection), and myocarditis-myositis-myasthenia gravis (or myasthenia-like) overlap syndrome. Severe or fatal cases have been reported for some of these reactions.
- **Infusion-Related Reactions:** TEVIMBRA can cause infusion-related reactions, which may be severe or life-threatening. Infusion-related reactions occurred in 4.7% of patients (Grade ≥3: 0.2%). Monitor patients during infusion; slow the infusion for Grade 1 reactions, interrupt the infusion for Grade 2, and permanently discontinue TEVIMBRA for Grade 3 or higher.

- **Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT):** Fatal and serious complications, including graft-versus-host disease, have occurred in patients who receive allogeneic HSCT before or after treatment with PD-1/PD-L1 blockade. Complications may occur despite intervening therapy between treatment with PD-1/PD-L1 blockade and allogeneic HSCT. Monitor patients closely and intervene promptly.
- **Embryo-Fetal Toxicity:** TEVIMBRA can cause fetal harm and potential fetal death as shown in animal studies. Advise females of reproductive potential of the potential risk to a fetus. Verify pregnancy status prior to initiation of TEVIMBRA. Advise females of reproductive potential to use effective contraception during treatment and for 4 months after the last dose.

ADVERSE REACTIONS

- The most common adverse reactions (≥20%), including lab abnormalities were:
- **Gastric, Gastroesophageal Junction, or Esophageal Adenocarcinoma (Combination with zanidatamab-hrii and chemotherapy, 1L):** diarrhea, nausea, anemia, decreased appetite, vomiting, hypokalemia, fatigue, rash, decreased neutrophil count, decreased platelet count, peripheral neuropathy, infusion-related reaction, and increased AST.
 - **Esophageal Cancer (Combination with chemotherapy, 1L):** 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.
 - **Gastric Cancer (Combination with chemotherapy, 1L):** nausea, fatigue, decreased appetite, anemia, peripheral sensory neuropathy, vomiting, decreased platelet count, decreased neutrophil count, increased AST, diarrhea, abdominal pain, increased ALT, decreased white blood cell count, decreased weight, and pyrexia.

SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed during treatment and for 4 months after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact BeOne Medicines at 1-877-828-5596 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for TEVIMBRA.

1L, first line; AR, adverse reaction; ESCC, esophageal squamous cell carcinoma; GC, gastric cancer; GEA, gastroesophageal adenocarcinoma; GEJC, gastroesophageal junction cancer; HER2, human epidermal growth factor receptor 2; IV, intravenous; PD-1, programmed death receptor 1; Q2W, every 2 weeks; Q3W, every 3 weeks; Q4W, every 4 weeks; Q6W, every 6 weeks; USP, United States Pharmacopeia.

References: **1.** TEVIMBRA. Prescribing Information. BeOne Medicines USA, Inc.; 2026. **2.** Keytruda. Prescribing Information. Merck & Co., Inc.; 2026. **3.** Opdivo. Prescribing Information. Bristol-Myers Squibb Company; 2026. **4.** Shitara K, Elimova E, Liu T, et al. *N Engl J Med.* 2026;394(20):2002-2014. doi:10.1056/NEJMoa2517729. **5.** Ziihera. Prescribing Information. Jazz Pharmaceuticals, Inc.; 2026.

