Tecentriq

(atezolizumab)

New Product Slideshow

MPR

Introduction

- **Brand name:** Tecentriq
- **Generic name:** Atezolizumab
- **Pharmacological class:** PD-L1 inhibitor
- **Strength and Formulation:** 60mg/mL; solution for IV infusion after dilution; preservative-free
- **Manufacturer:** Genentech
- **How supplied:** Single-dose vial (20mL)—1
- **Legal Classification:** Rx

TECENTRIQ


NDC 50242-917-01
Tecentriq™
(atezolizumab)
Injection
1200 mg / 20 mL
(60 mg / mL)
For Intravenous Infusion After Dilution
Single-Dose Vial
Discard Unused Portion

Indications

- 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

Dosage & Administration

- Give as IV infusion over 60 minutes
- 1200mg every 3 weeks until disease progression or unacceptable toxicity
- May give subsequent infusions over 30 minutes if first infusion tolerated

Considerations for Special Populations

- **Pregnancy:** Can cause fetal harm
- **Nursing mothers:** Not recommended during and for ≥5 months after final dose
- **Pediatric:** Not established
- **Geriatric:** No overall differences in safety and efficacy
- **Hepatic impairment:** Moderate or severe impairment: not studied

Warnings/Precautions

- Permanently discontinue if:
  - Grade 3/4 pneumonitis
  - AST or ALT >5×ULN or total bilirubin >3×ULN
  - Grade 4 diarrhea or colitis
  - Grade 4 hypophysitis
  - Myasthenic syndrome/myasthenia gravis
  - Guillain-Barre or meningoencephalitis
  - Grade 3/4 ocular inflammatory toxicity
  - Grade 4 or recurrent pancreatitis
  - Grade 3/4 infusion-related reactions
  - Grade 4 rash

Warnings/Precautions

- Withhold for:
  - Grade 2 pneumonitis
  - AST or ALT >3–5×ULN or total bilirubin >1.5–3×ULN
  - Grade 2/3 diarrhea or colitis
  - Symptomatic hypophysitis
  - Adrenal insufficiency
  - Hypothyroidism
  - Hyperthyroidism

Warnings/Precautions

- Withhold for (cont'd):
  - Grade 3/4 hyperglycemia
  - Grade 2 ocular inflammatory toxicity
  - Grade 2/3 pancreatitis or Grade 3/4 increases in amylase or lipase levels (>2×ULN)
  - Grade 3/4 infection
  - Grade 2 infusion-related reactions
  - Grade 3 rash
- May be resumed when recover to Grade 0–1

Warnings/Precautions

- **Monitor** for immune-related pneumonitis, hepatitis (obtain AST, ALT, bilirubin prior to and during treatment), diarrhea or colitis, endocrinopathies (hypophysitis, thyroid function, adrenal insufficiency, diabetes), meningitis or encephalitis, motor and sensory neuropathy, and acute pancreatitis
- Give corticosteroids at 1–2mg/kg/day prednisone or equivalent, thyroid hormone replacement, or insulin based on related-reaction and severity of event (see full labeling)

Warnings/Precautions

- Monitor for infections and treat appropriately
- Interrupt or slow the infusion rate if mild or moderate infusion reactions occur
- Embryo-fetal toxicity
- Use effective contraception during and for ≥5 months after final dose

Adverse Reactions

- Fatigue
- Decreased appetite
- Nausea
- Urinary tract infection
- Pyrexia
- Constipation
- Lab abnormalities

Mechanism of Action

- Atezolizumab is a monoclonal antibody that binds to PD-L1 and blocks its interactions with both PD-1 and B7.1 receptors
- This releases the PD-L1/PD-1 mediated inhibition of the immune response, including activation of the anti-tumor immune response without inducing antibody-dependent cellular cytotoxicity

Clinical Trials

- Tecentriq was evaluated in **Study 1**, a multicenter, open-label, 2-cohort trial that included patients with locally advanced or metastatic urothelial carcinoma

- Patients in Cohort 2 (n=310) received Tecentriq 1200mg IV every 3 weeks until unacceptable toxicity or either radiographic or clinical progression

Clinical Trials

- Major **efficacy outcome measures** included confirmed objective response rate (ORR) using RECIST v1.1 and duration of response
- Tumor assessments were conducted every 9 weeks for the first 54 weeks and every 12 weeks thereafter

Clinical Trials

- Of the total patients, ORR was **14.8%** (95% CI: 11.1, 19.3) with **5.5%** achieving complete response and **9.4%** achieving partial response

Clinical Trials

- Among the two PD-L1 subgroups, ORR was **9.5%** (95% CI: 5.9, 14.3) in the PD-L1 expression of <5% in ICs group and **26.0%** (95% CI: 17.7, 35.7) in the PD-L1 expression of ≥5% in ICs group
- In patients with disease progression after neoadjuvant or adjuvant therapy (n=59), ORR was **22.0%** (95% CI: 12.3, 34.7)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/tecentriq/drug/34572/