

16 HOW SUPPLIED/STORAGE AND HANDLING

TECENTRIQ injection is a sterile, preservative-free, and colorless to slightly yellow solution for intravenous infusion supplied as a carton containing one 840 mg/14 mL single-dose vial (NDC 50242-918-01) or 1,200 mg/20 mL single-dose vial (NDC 50242-917-01).

Store vials under refrigeration at 2°C to 8°C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not shake.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Immune-Mediated Adverse Reactions

Inform patients of the risk of immune-mediated adverse reactions that may require corticosteroid treatment and interruption or discontinuation of TECENTRIQ, including:

- **Pneumonitis:** Advise patients to contact their healthcare provider immediately for any new or worsening cough, chest pain, or shortness of breath [*see Warnings and Precautions (5.1)*].
- **Colitis:** Advise patients to contact their healthcare provider immediately for diarrhea, blood or mucus in stools, or severe abdominal pain [*see Warnings and Precautions (5.1)*].
- **Hepatitis:** Advise patients to contact their healthcare provider immediately for jaundice, severe nausea or vomiting, pain on the right side of abdomen, lethargy, or easy bruising or bleeding [*see Warnings and Precautions (5.1)*].
- **Endocrinopathies:** Advise patients to contact their healthcare provider immediately for signs or symptoms of hypophysitis, hyperthyroidism, hypothyroidism, adrenal insufficiency, or type 1 diabetes mellitus, including diabetic ketoacidosis [*see Warnings and Precautions (5.1)*].
- **Nephritis:** Advise patients to contact their healthcare provider immediately for pelvic pain, frequent urination, or unusual swelling. [*see Warnings and Precautions (5.1)*].
- **Dermatologic Adverse Reactions:** Advise patients to contact their healthcare provider immediately for generalized rash, skin eruption, or painful skin and mucous membrane lesions [*see Warnings and Precautions (5.1)*].
- **Other Immune-Mediated Adverse Reactions:** Advise patients to contact their healthcare provider immediately for signs or symptoms of other potential immune-mediated adverse reactions [*see Warnings and Precautions (5.1)*].

Infusion-Related Reactions

Advise patients to contact their healthcare provider immediately for signs or symptoms of infusion-related reactions [*see Warnings and Precautions (5.2)*].

Complications of Allogeneic HSCT after PD-1/PD-L1 inhibitors

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefits versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT [*see Warnings and Precautions (5.3)*].

Embryo-Fetal Toxicity

Advise females of reproductive potential that TECENTRIQ can cause harm to a fetus and to inform their healthcare provider of a known or suspected pregnancy [*see Warnings and Precautions (5.4), Use in Specific Populations (8.1, 8.3)*].

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For more information, call 1-844-832-3687 or go to www.TECENTRIQ.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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