יולי 2021

Tecentriq® 60mg/ml
atezolizumab
Concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים שבוצעו בעלון לרופא של התכשיר טיסנטריק המתייחסים לשינויים במשטר המינון.

בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויות הרשומות לתכשיר בישראל:

Urothelial Carcinoma

- TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumours have a PD-L1 expression ≥ 5%.
- TECENTRIQ is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy

Non-Small Cell Lung Cancer

- TECENTRIQ, as a single agent, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an approved test, with no EGFR or ALK genomic tumor aberrations.
- TECENTRIQ, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, TECENTRIQ, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated only after failure of appropriate targeted therapies.
- TECENTRIQ, in combination with paclitaxel protein-bound and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
- TECENTRIQ is indicated for the treatment of patients with metastatic NSCLC who are naïve to anti-PD-L1 or anti-PD-1 therapies and have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for NSCLC harboring these aberrations prior to receiving TECENTRIQ.

Locally Advanced or Metastatic Triple-Negative Breast Cancer

TECENTRIQ, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors have PD-L1 expression ≥1% and who have not received prior chemotherapy for metastatic disease.

Small Cell Lung Cancer

TECENTRIQ, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Hepatocellular Carcinoma

TECENTRIQ, in combination with bevacizumab, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Melanoma

TECENTRIQ, in combination with cobimetinib and vemurafenib, is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

למידע נוסף יש לעיין בעלון לרופא כפי שנשלח למשרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד 6391 , הוד השרון 4524079
טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

לילי אדר
רוקחת ממונה

בתאור צפרי-חגג
מחלקת רישום

עדכונים מהותיים בעלון לרופא

בסעיף DOSAGE AND ADMINISTRATION עודכן המידע הבא:

2.2 Recommended Dosage for Urothelial Carcinoma

The recommended dosage of TECENTRIQ is:

- 840 mg every 2 weeks or
- 1200 mg every 3 weeks or
- 1680 mg every 4 weeks

administered intravenously over 60 minutes until disease progression or unacceptable toxicity. If the first infusion is tolerated, all subsequent infusions may be delivered over 30 minutes.

2.3 Recommended Dosage for NSCLC

Single Agent

The recommended dosage of TECENTRIQ is:

- 840 mg every 2 weeks or
- 1200 mg every 3 weeks or
- 1680 mg every 4 weeks

administered intravenously over 60 minutes until disease progression or unacceptable toxicity. If the first infusion is tolerated, all subsequent infusions may be delivered over 30 minutes.

TECENTRIQ with Platinum-based Chemotherapy

The recommended dosage of TECENTRIQ is 1200 mg intravenously every 3 weeks until disease progression or unacceptable toxicity.

Administer TECENTRIQ prior to chemotherapy and bevacizumab when given on the same day. Refer to the Prescribing Information for the chemotherapy agents or bevacizumab administered in combination with TECENTRIQ for recommended dosing information.

Following completion of 4-6 cycles of chemotherapy, and if bevacizumab is discontinued, the recommended dosage of TECENTRIQ is:

- 840 mg every 2 weeks or
- 1200 mg every 3 weeks or
- 1680 mg every 4 weeks

administered intravenously until disease progression or unacceptable toxicity.

Administer the initial infusion of TECENTRIQ over 60 minutes. If the first infusion is tolerated, all subsequent infusions may be delivered over 30 minutes.