



ינואר 2022

**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 לנושא מיהול התכשיר. בנוסף, בהמשך להודעה על עדכון התוכנית למזעור סיכונים, בוטלה ההפנייה לחוברת מידע לרופא. 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  $\geq 5\%$ .
- 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  $\geq 50\%$  of tumor cells [TC  $\geq 50\%$ ] or PD-L1 stained tumor-infiltrating immune cells [IC] covering  $\geq 10\%$  of the tumor area [IC  $\geq 10\%$ ]), 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  $\geq 1\%$  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](http://www.roche.co.il).

ב ב ר כ ה,



לילי אדר  
רוקחת ממונה



בתאור צפרי-חגג  
מחלקת רישום

## עדכונים מהותיים בעלון לרופא

### בסעיף **QUALITATIVE AND QUANTITATIVE COMPOSITION** עודכן המידע הבא:

One vial of 20 mL of concentrate contains 1,200 mg atezolizumab. After dilution, the final concentration of the diluted solution should be between 3.2 and 16.8 mg/mL, one mL of solution contains approximately 4.4 mg of atezolizumab.

One 14 mL vial of concentrate contains 840 mg of atezolizumab. After dilution, the final concentration of the diluted solution should be between 3.2 and 16.8 mg/mL, one mL of solution contains approximately 3.2 mg of atezolizumab.

### בסעיף **DOSAGE AND ADMINISTRATION** עודכן המידע הבא:

#### **2.9 Preparation and Administration**

##### Preparation

Visually inspect drug product for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard the vial if the solution is cloudy, discolored, or visible particles are observed. Do not shake the vial.

Prepare the solution for infusion as follows:

- Select the appropriate vial(s) based on the prescribed dose.
- Withdraw the required volume of TECENTRIQ from the vial(s) using sterile needle and syringe.
- Dilute into a 250 mL to a final concentration between 3.2 mg/mL and 16.8 mg/mL in a polyvinyl chloride (PVC), polyethylene (PE), or polyolefin (PO) infusion bag containing 0.9% Sodium Chloride Injection, USP.
- Dilute with only 0.9% Sodium Chloride Injection
- Mix diluted solution by gentle inversion. Do not shake.
- Discard used or empty vials of TECENTRIQ.

##### Storage of Infusion Solution

This product does not contain a preservative.

Administer immediately once prepared. If diluted TECENTRIQ infusion solution is not used immediately, store solution either:

- At room temperature ( $\leq 25^{\circ}\text{C}$ ) for no more than 8 up to 24 hours from the time of preparation. This includes room temperature storage of the infusion in the infusion bag and time for administration of the infusion, or
- Under refrigeration at  $2^{\circ}\text{C}$ - $8^{\circ}\text{C}$  for no more than 24 hours up to 30 days from time of preparation.
- From a microbiological point of view, the prepared solution for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  or 8 hours at ambient temperature ( $\leq 25^{\circ}\text{C}$ ) unless dilution has taken place in controlled and validated aseptic conditions.

Do not freeze. Do not shake.