

Tecentriq® (Atezolizumab)
Concentrate for solution for infusion
(60mg/ml)

חפאה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על רישום התוויה נוספת לתכשיר טיסנטריק לטיפול בחולי סרטן מסוג NSCLC עם ביטוי יתר של PD-L1 בשלב מחלה מוקדם.

להלן רשימת ההתוויות המלאה של התכשיר (ההתוויה החדשה מודגשת):

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 monotherapy, is indicated as adjuvant treatment following complete resection and no progression after platinum-based adjuvant chemotherapy for adult patients with Stage II to IIIA NSCLC whose tumors have PD-L1 expression on $\geq 50\%$ of tumor cells (TCs).**
- 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.

כפועל יוצא של עדכון ההתוויות העליון לרופא של התכשיר טיסנטריק עודכן בסעיפים נוספים. למידע מלא יש לעיין בעלון לרופא המצורף להודעה זו.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי 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 ,



בתאור צפרי-חגג
מחלקת רישום



לילי אדר
רוקחת ממונה