ספטמבר 2026

רופא/ה רוקח/ת נכבד/ה,

חברת בי-וואן מדיסינז ישראל בע"מ, שמחה להודיעך על אישור התוויה חדשה לתכשיר:

TEVIMBRA

Concentrate for solution for infusion

Tislelizumab 10mg/ml **החומר הפעיל וריכוזו:**

ההתוויה החדשה:

Non-small cell lung cancer (NSCLC)

Tevimbra, in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of adult patients with resectable NSCLC at high risk of recurrence.

ההתוויות המאושרות:

Non-small cell lung cancer (NSCLC)

Tevimbra in combination with carboplatin and either paclitaxel or nab-paclitaxel is indicated for the first-line treatment of adult patients with squamous NSCLC who have:

•locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or •metastatic NSCLC.

Tevimbra as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior platinum-based therapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving tislelizumab

Small Cell Lung Cancer (SCLC)

Tevimbra, in combination with etoposide and platinum chemotherapy, is indicated for the first-line treatment of adult patients with extensive-stage SCLC.

Oesophageal squamous cell carcinoma (OSCC)

Tevimbra, in combination with platinum-containing chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (OSCC) whose tumours express PD-L1 (≥1).

Tevimbra as monotherapy is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic OSCC after prior platinum-based chemotherapy.

Gastric cancer or gastroesophageal junction adenocarcinoma (G/GEJ)

Tevimbra in combination with platinum and fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express PD-L1 (≥1).

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בעקבות אישור ההתוויה החדשה עודכן סעיף 4.2 (תוספת מסומנת באדום):

4.2 Posology and method of administration

Tevimbra monotherapy

The recommended dose of Tevimbra is 200 mg administered by intravenous infusion once every 3 weeks. For resectable NSCLC, during the adjuvant treatment phase, the recommended dose of Tevimbra is 400 mg administered by intravenous infusion once every 6 weeks.

[…]

Duration of treatment

Patients should be treated with Tevimbra until disease progression or unacceptable toxicity (see section 5.1). For the neoadjuvant and adjuvant treatment of resectable NSCLC, patients should be treated with neoadjuvant Tevimbra (200 mg every 3 weeks) in combination with chemotherapy for 3 or 4 cycles or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with Tevimbra (400 mg every 6 weeks) as monotherapy for up to 8 cycles or until disease recurrence, metastasis, or unacceptable toxicity.

[…]

Method of administration

[…]

The first infusion should be administered over a period of 60 minutes. If this is well tolerated, the subsequent infusions may be administered over a period of 30 minutes. The infusion should be given via an intravenous line containing a sterile, non-pyrogenic, low-protein-binding 0.2 or 0.22 micron in-line or add-on filter. The infusion of an initial dose of Tevimbra 400 mg should be delivered over 120 minutes (over 90 minutes if it is used as subsequent treatment after the dose of 200 mg once every 3 weeks). If well tolerated, the second infusion may be administered over 60 minutes. If the second infusion is well tolerated, subsequent infusions may be administered over 30 minutes.

כמו כן, נעשו עדכונים נוספים בעלון לרופא. בהודעה זו מפורטים העדכונים המהווים החמרה במידע בטיחותי בלבד (מסומנים במרקר צהוב), למידע מלא יש לעיין בעלון לרופא.

4.8 Undesirable effects

[…]

The safety of tislelizumab given in combination with chemotherapy is based on data in 1950 patients across multiple tumour types who received 200 mg tislelizumab every 3 weeks, with the exception of study BGB A317-315 where patients also received ~~other dosage regimens~~ tislelizumab at a dose of 400 mg once every 6 weeks as adjuvant treatment after neoadjuvant therapy and surgery.

[…]

Immunogenicity

[…]

Among ADA-evaluable patients receiving 200 mg once every 3 weeks monotherapy or in combination with chemotherapies (including ~~other dosage regimens~~ adjuvant 400 mg once every 6 weeks in resectable NSCLC) the following rates of adverse events (AEs) have been observed for the ADA-positive population compared to the ADA-negative population, respectively

[…]

5.2 Pharmacokinetic properties

[…]

Linearity/non-linearity

At the dosing regimens of 0.5 mg/kg to 10 mg/kg once every 2 or 3 weeks (including 200 mg once every 3 weeks and at 400 mg once every 6 weeks), the PK of tislelizumab were observed to be linear and the exposure was dose proportional.

6.6 Special precautions for disposal and other handling

[…]

Preparation of solution for infusion

- ~~Two Tevimbra vials are required for each dose.~~
- Remove the required number of vials from the refrigerator, taking care not to shake them.
- Inspect each vial visually for particulate matter and discolouration prior to administration. The concentrate is a clear to slightly opalescent, colourless to slightly yellowish solution. Do not use a vial if the solution is cloudy, or if visible particles or discolouration are observed.
- Invert the vials gently without shaking. Withdraw the ~~solution~~ required volume from the ~~two vials (a total of 200 mg in 20 ml)~~ vial(s) into a syringe and transfer into an intravenous infusion bag containing sodium chloride 9 mg/ml (0.9%) solution for injection, to prepare a diluted solution with a final concentration ranging from 2 to 5 mg/ml. Mix diluted solution by gentle inversion to avoid foaming or excessive shearing of the solution.

Administration

[…]

- ~~The~~ For 200 mg once every 3 weeks, the first infusion should be delivered over 60 minutes. If well tolerated, subsequent infusions may be administered over 30 minutes.

The infusion of an initial dose of Tevimbra 400 mg should be delivered over 120 minutes (over 90 minutes if it is used as subsequent treatment after the dose of 200 mg once every 3 weeks). If well tolerated, the second infusion may be administered over 60 minutes. If the second infusion is well tolerated, subsequent infusions may be administered over 30 minutes.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות:

https://israeldrugs.health.gov.il/#!/medDetails/177%2072%2037815%2000

כמו כן ניתן לקבל את העלון המודפס על ידי פניה לבעל הרישום: בי- וואן מדיסינז ישראל בע"מ, מדינת היהודים 89, הרצליה.

בברכה,

בי- וואן מדיסינז ישראל בע"מ