

ויל' 2024

רופא/ה יקר/ה
רוקח/ת יקר/ה,**KEYTRUDA® 100 mg/4 mL**
קייטרודה 100 מ"ג/4 מ"ל**Dosage form and Composition:**

Pembrolizumab 100 mg/4 ml; Concentrate for Solution for Intravenous Infusion

חברת מרכז רפואי דודו (ישראל-1996) בע"מ, (MSD ישראל), מבקשת לידע על עדכון העלון לרופא ולצורך של התכשיר Keytruda 100mg/4ml המפורט מטה.

(טקסט שהועסף לעלון לרופא ולצורך מודגש בכו תחתון, טקסט שנמחק מהעלון לרופא ולצורך מסומן בכו חוצה)

עדכנים שבסעינו לעלון לרופא:**1 THERAPEUTIC INDICATIONS**

[...]

1.6 Urothelial Carcinoma Cancer

KEYTRUDA, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (CPS ≥ 10) as determined by a validated test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

KEYTRUDA, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

KEYTRUDA, as a single agent, is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

[...]

1.9 Gastric cancer

KEYTRUDA, in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction (GEJ) adenocarcinoma in adults whose tumors express PD-L1 with a CPS ≥ 1 as determined by a validated test.

[...]

12.3 Pharmacokinetics

[...]

Specific Populations

The following factors had no clinically important effect on the CL of pembrolizumab: age (range: 15 to 94 years), sex, race (89% White), renal impairment (eGFR ≥ 15 mL/min/1.73 m²), mild to moderate hepatic impairment (total bilirubin \leq upper limit of normal (ULN) and AST $>$ ULN or total bilirubin between 1 and 1.53 times ULN and any AST), or tumor burden. The impact of moderate or severe hepatic impairment (total bilirubin $>$ 3 times ULN and any AST) on the pharmacokinetics of pembrolizumab is unknown.

עדכנים שבסעינו לעלון לצרכן:**1. למה מיועדת קיטרודה?**

קייטרודה הינה תרופה מרשם המשמש לטיפול ב:

[...]

• סרטן שלפוחית השטן ודרכי השטן (urothelial carcinoma cancer).

• ניתן להשתמש בקייטרודה לבדה כאשר סרטן שלפוחית השטן או דרכי השטן שלר:

היתפסת או שאין אפשרות להסירו על ידי ניתוח (سرطان מתקדם של דרכי השטן) **ו**

- אין יכול לקבל כימותרפיה המכילת תרופה שנקראת ציספלטין, והגידול חיובי **ל-** "PD-L1", **ו**
- אין יכול לקבל תרופה שנקראת ציספלטין או קרבופלטין (ללא תלות ב "PD-L1"), **ו**
- **המחלה התקדמתה** במהלך או לאחר **שקבלת כימותרפיה המכילת פלטינום**.

ו **ניתן להשתמש בKEYTRUDA** **לבדה** אם הסרטן שלך לא התפסת לירקמה סמוכה בשלפוחית השטן, אך נמצא בסיכון גבוה להחטפותו (سرطان שלפוחית השטן שנין חודר שיר [NMIBC] בסיכון גבוה) כאשר:

- הגידול שלך הוא מסוג קרצינומה ממקומת ("carcinoma in situ"), **ו גם**
- ניסית טיפול ב- BCG (Bacillus Calmette-Guerin) אשר לא עבד, **ו גם**
- איןך כשיר או שבחרת שלא לעבור ניתוח לכיריתת שלפוחית השטן שלך.

ו **ניתן להשתמש בKEYTRUDA** **כאשר** סרטן שלפוחית השטן או דרכי השטן **שלך:**

- **היתפסת או שאין אפשרות להסירו על ידי ניתוח (سرطان מתקדם של דרכי השטן) **ו****
- **איןך יכול לקבל כימותרפיה המכילת תרופה שנקראת ציספלטין, והגידול חיובי **ל-** "PD-L1", **ו****
- **איןך יכול לקבל תרופה שנקראת ציספלטין או קרבופלטין (ללא תלות ב "PD-L1"), **ו****
- **המחלה התקדמתה** **במהלך או לאחר** **שקבלת כימותרפיה המכילת פלטינום.**

התווויות המאושרות למכשיר:Melanoma

- KEYTRUDA is indicated for the treatment of adult and pediatric (12 years and older) patients with unresectable or metastatic melanoma.
- KEYTRUDA is indicated for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC, or III melanoma following complete resection.

Non-Small Cell Lung Cancer

- KEYTRUDA, in combination with pemetrexed and carboplatin, is indicated for the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC) negative for EGFR or ALK genomic tumor aberrations.
- KEYTRUDA, in combination with carboplatin and either paclitaxel or paclitaxel protein-bound, is indicated for the first-line treatment of patients with metastatic squamous NSCLC.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 [Tumor Proportion Score (TPS) $\geq 50\%$] as determined by a validated test. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on or after platinum-containing chemotherapy and an approved therapy for these aberrations prior to receiving KEYTRUDA.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with advanced NSCLC whose tumors express PD-L1 as determined by a validated test, with disease progression on or after platinum containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving KEYTRUDA.
- KEYTRUDA, as a single agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIA NSCLC.

Head and Neck Cancer

- KEYTRUDA, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).
- KEYTRUDA, as a single agent, is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by a validated test.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

Classical Hodgkin Lymphoma

- KEYTRUDA is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL).
- KEYTRUDA is indicated for the treatment of pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy.

Primary Mediastinal large B-Cell Lymphoma

KEYTRUDA is indicated for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after 2 or more prior lines of therapy.

Limitation of Use: KEYTRUDA is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.

Urothelial Cancer

- KEYTRUDA, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS \geq 10)] as determined by a validated test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with Bacillus Calmette-Guerin (BCG) unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Microsatellite Instability-High Cancer

KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

- solid tumors that have progressed following prior systemic treatment and who have no satisfactory alternative treatment options,
or
- colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Limitation of Use: The safety and effectiveness of KEYTRUDA in pediatric patients with MSI-H central nervous system cancers have not been established.

Gastric Cancer

- KEYTRUDA, in combination with trastuzumab, fluoropyrimidine and platinum-containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction (GEJ) adenocarcinoma in adults whose tumors express PD-L1 with a CPS \geq 1 as determined by a validated test.

Cervical Cancer

- KEYTRUDA, in combination with chemotherapy, with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS \geq 1) as determined by a validated test
- KEYTRUDA, as a single agent, is indicated for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS \geq 1) as determined by a validated test.

Biliary Tract Cancer

KEYTRUDA, in combination with gemcitabine and cisplatin, is indicated for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer (BTC).

Merkel Cell Carcinoma

KEYTRUDA is indicated for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC).

Renal Cell Carcinoma

- KEYTRUDA, in combination with axitinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).
- KEYTRUDA, in combination with lenvatinib, is indicated for the first-line treatment of adult patients with advanced RCC.
- KEYTRUDA is indicated for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

Esophageal Cancer

- KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) (Siewert type I) carcinoma that is not amenable to surgical resection or definitive chemoradiation in combination with platinum- and fluoropyrimidine-based chemotherapy.
- KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (CPS \geq 10) as determined by a validated test, with disease progression after one or more prior lines of systemic therapy.

Cutaneous Squamous Cell Carcinoma

KEYTRUDA is indicated for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC that is not curable by surgery or radiation.

Microsatellite Instability-High or Mismatch Repair Deficient Colorectal Cancer (CRC)



KEYTRUDA is indicated for the first-line treatment of patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC).

Tumor Mutational Burden-High Cancer

KEYTRUDA is indicated for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] solid tumors, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.

Limitations of Use: The safety and effectiveness of KEYTRUDA in pediatric patients with TMB-H central nervous system cancers have not been established.

Triple Negative Breast Cancer

- KEYTRUDA, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic triple negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥ 10) as determined by a validated test.
- KEYTRUDA is indicated for the treatment of patients with high risk early stage triple negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.

Endometrial carcinoma

Keytruda, in combination with lenvatinib, is indicated for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum containing therapy and who are not candidates for curative surgery or radiation.

בעלונים לרופא ולצורך בוצעו עידכונים נוספים שאינם נכללים בהודעה זו.
למידע מלא ולהוראות מתן מפורטות, יש לעיין בעלון לרופא ולצורך המאושרם על ידי משרד הבריאות.

העלונים לרופא ולצורך נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, ונitin לקבלת מודפסים על ידי פניה לבעל הרישום, חברת MSD, טלפון 95333333-09.

Keytruda 100mg/4ml מופצת ע"י חברת נובלוג בע"מ.

בברכה,
דורית מאורי
רוקחת ממונה
MSD ישראל

References:

Keytruda_100mg_4ml-SPC-07_2024_clean
Keytruda_100mg_4ml-PIL-HEB-07_2024_clean