

אפריל 2024

OPDIVO
Concentrate for solution for infusion
אופדיבו
תמיסה מרוכזת להכנת תמיסה לעירוי

רופא/ה, רוקח/ת יקר/ה,

חברת בריסטול-מאייירס סקוויב (ישראל) מבקשת להודיע על עדכון בעלון לרופא של התכשיר שבנדון.
 להלן התוויות התכשיר כפי שמאושרות ע"י משרד הבריאות:

Unresectable or Metastatic Melanoma

OPDIVO, as monotherapy or in combination with ipilimumab is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults and pediatric patients 12 years and older.

Adjuvant Treatment of Melanoma

OPDIVO is indicated for the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, IIC, III, or IV melanoma.

Neoadjuvant Treatment of Resectable Non-Small Cell Lung Cancer

OPDIVO, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer (NSCLC).

Metastatic Non-Small Cell Lung Cancer

- OPDIVO, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
- OPDIVO is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.

Malignant Pleural Mesothelioma

OPDIVO, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

Advanced Renal Cell Carcinoma

- OPDIVO, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with intermediate or poor risk advanced renal cell carcinoma (RCC).
- OPDIVO, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced RCC.
- OPDIVO as a single agent is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

Classical Hodgkin Lymphoma

OPDIVO is indicated for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after:

- autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or
- 3 or more lines of systemic therapy that includes autologous HSCT.

Squamous Cell Carcinoma of the Head and Neck

OPDIVO is indicated for the treatment of adult patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

Urothelial Carcinoma

- OPDIVO is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC.
- OPDIVO (Nivolumab) is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:
 - have disease progression during or following platinum-containing chemotherapy
 - have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer

OPDIVO, as a single agent or in combination with ipilimumab, is indicated for the treatment of adult and pediatric patients 12 years and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Hepatocellular Carcinoma

OPDIVO, as a single agent or in combination with ipilimumab, is indicated for the treatment of adult patients with hepatocellular carcinoma (HCC) Child-Pugh A who have been previously treated with sorafenib.

Esophageal Cancer

- OPDIVO is indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult patients who have received neoadjuvant chemoradiotherapy (CRT).
- OPDIVO in combination with fluoropyrimidine- and platinum-based combination chemotherapy is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) with tumor cell PD-L1 expression $\geq 1\%$.
- OPDIVO in combination with ipilimumab is indicated for the first-line treatment of adult patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) with tumor cell PD-L1 expression $\geq 1\%$.
- OPDIVO is indicated for the treatment of adult patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

OPDIVO, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of adult patients with unresectable advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.

המרכיב הפעיל: Nivolumab 10mg/ml

השינוי העיקרי בעלון לרופא משוקף בעמוד הבא.

תוספת טקסט מסומנת בקו **תחתון אדום**, והחמרה מודגשת ב**צהוב**.
 העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד-הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום בריסטול-מאירס סקוויב (ישראל) בע"מ.

בברכה,

לנה גיטלין
 מנהלת רגולציה ורוקחת ממונה
 בריסטול-מאירס סקוויב (ישראל)

OPDIVO (nivolumab 10 mg/mL)
Concentrate for solution for infusion

FULL PRESCRIBING INFORMATION

[...]

5 WARNINGS AND PRECAUTIONS

5.1 Severe and Fatal Immune-Mediated Adverse Reactions

[...]

Other Immune-Mediated Adverse Reactions

[...]

Other (Hematologic/Immune): Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, **other transplant (including corneal graft) rejection**