אוגוסט 2026

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

רופא/ה ,רוקח/ת יקר/ה,

חברת בריסטול-מאיירס סקוויב (ישראל) מתכבדת להודיע על עדכון עלונים לרופא ולצרכן של התכשיר אופדיבו.
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 adult 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).

Neoadjuvant and Adjuvant Treatment of Resectable Non-Small Cell Lung Cancer

OPDIVO, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) NSCLC with tumour cell PD-L1 expression ≥ 1% and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent OPDIVO as adjuvant treatment after surgery.

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.

Advanced Renal Cell Carcinoma

- 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.
- 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.

Classical Hodgkin Lymphoma

- OPDIVO in combination with doxorubicin, vinblastine and dacarbazine (AVD) is indicated for the treatment of adult and pediatric patients 12 years and older with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL).
- OPDIVO, as a single agent, 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.

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

- OPDIVO, in combination with ipilimumab, is indicated for the first-line treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC).
- 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.

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, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.
- OPDIVO 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.

Hepatocellular Carcinoma

- OPDIVO, 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.

- OPDIVO, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with Child-Pugh A unresectable or metastatic hepatocellular carcinoma (HCC).

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 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.
- 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 ≥ 1%.
- 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 ≥ 1% .

Malignant Pleural Mesothelioma

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

Gastric Cancer, Gastroesophageal Junction Cancer, and EsophagealAdenocarcinoma

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

העלונים לרופא ולצרכן עודכנו בנוגע לתנאי האחסון והיציבות לאחר הכנה לשימוש של התכשיר (in-use stability) וכן בוצעו עדכונים עריכתיים.

השינויים העיקריים בעלון לרופא ובעלון לצרכן משוקפים בעמודים הבאים. תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט ~~בקו חוצה~~.

העלון לרופא והעלון לצרכן הנקיים נשלחו לפרסום במאגר התרופות שבאתר משרד-הבריאות וניתן לקבלם מודפסים על ידי פניה לבעל הרישום בריסטול-מאיירס סקוויב (ישראל) בע"מ.

בברכה,

לנה גיטלין

מנהלת רגולציה ורוקחת ממונה
בריסטול-מאיירס סקוויב (ישראל)

עדכונים בעלון לרופא:

2.4 Preparation and Administration

...

OPDIVO may be administered either without dilution or after dilution as described below.

...

- ~~After preparation, store the diluted solution either:~~
  - ~~at room temperature at 20°C to 25°C and room light for no more than 8 hours from the time of preparation to end of the infusion. Discard diluted solution if not used within 8 hours from the time of preparation; or~~
  - ~~under refrigeration at 2°C to 8°C and protected from light for no more than 7 days from the time of preparation to end of infusion. Discard diluted solution if not used within 7 days from the time of preparation.~~
- After preparation of infusion:

  Chemical and physical in-use stability from the time of preparation has been demonstrated as follows (times are inclusive of the administration period):

Infusion preparation	**Chemical and physical in-use stability**	
	Storage at 2ºC to 8ºC protected from light	**Storage at room temperature (≤ 25°C) and room light**
Undiluted or diluted with sodium chloride 9 mg/mL (0.9%) solution for injection	30 days	24 hours (of total 30 days storage)
Diluted with 50 mg/mL (5%) glucose solution for injection	7 days	8 hours (of total 7 days storage)

  From a microbiological point of view the prepared solution for infusion, regardless of the diluent, 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 7 days at 2°C to 8°C or 8 hours (of the total 7 days of storage) at room temperature (≤ 25°C). Aseptic handling should be ensured during the preparation of infusion.

...

Administration

- Administer the infusion~~, after dilution~~, over 30 minutes or 60 minutes depending on the dose (see Tables 1 and 2) through an intravenous line containing a sterile, non-pyrogenic, low protein binding in-line filter (pore size of 0.2 micrometer to 1.2 micrometer).

...

11 DESCRIPTION

...

OPDIVO (nivolumab) injection for intravenous use is supplied in single-dose vials. Each mL of OPDIVO solution contains nivolumab 10 mg, mannitol (30 mg), sodium citrate dihydrate (5.88 mg), sodium chloride (2.92 mg), polysorbate 80 (0.2 mg), pentetic acid (0.008 mg), ~~polysorbate 80 (0.2 mg), sodium chloride (2.92 mg), sodium citrate dihydrate (5.88 mg),~~ and

Water for Injection, USP. May contain hydrochloric acid and/or sodium hydroxide to adjust pH to 6.

...

16 HOW SUPPLIED/STORAGE AND HANDLING

...

Store under refrigeration at 2°C to 8°C (36°F to 46°F). Protect from light by storing in the original package until time of use. Do not freeze or shake.

The unopened vial can be stored at controlled room temperature up to 25°C with room light for up to 48 hours.

...

After preparation of infusion:

Chemical and physical in-use stability from the time of preparation has been demonstrated as follows (times are inclusive of the administration period):

Infusion preparation	**Chemical and physical in-use stability**	
	Storage at 2ºC to 8ºC protected from light	**Storage at room temperature (≤ 25°C) and room light**
Undiluted or diluted with sodium chloride 9 mg/mL (0.9%) solution for injection	30 days	24 hours (of total 30 days storage)
Diluted with 50 mg/mL (5%) glucose solution for injection	7 days	8 hours (of total 7 days storage)

From a microbiological point of view the prepared solution for infusion, regardless of the diluent, 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 7 days at 2°C to 8°C or 8 hours (of the total 7 days of storage) at room temperature (≤ 25°C). Aseptic handling should be ensured during the preparation of infusion.

~~The administration of the OPDIVO infusion (undiluted or diluted with 0.9% Sodium Chloride Injection (NS) or 5% Dextrose Injection (D5W)) must be completed within 7 days of preparation. If not used immediately, the solution may be stored under refrigeration conditions: 2°C to 8°C and protected from light for up to 7 days (a maximum of 8h of the total 7 days can be at room temperature 20°C to 25°C and room light – the maximum 8h period under room temperature and room light conditions should be inclusive of the product administration period).~~

עדכונים בעלון לצרכן:

...

1. איך לאחסן את התרופה?

...

- **תנאי אחסון:** יש לשמור בקירור ב-2°C-8°C. יש להגן מפני אור על-ידי אחסון הבקבוקון באריזה המקורית עד לזמן השימוש. ניתן לאחסן את הבקבוקון הסגור בטמפרטורת חדר מבוקרת של עד 25°C, בחשיפה לתאורת חדר, למשך עד 48 שעות.
- ~~אחרי ההכנה של העירוי: יש להשלים את מתן העירוי תוך 7 ימים מרגע ההכנה. אם העירוי לא ניתן מיידית, ניתן לאחסן את אופדיבו לאחר הכנה:~~
~~בטמפרטורת חדר (20°C-25°C) ותאורת חדר לפרק זמן של לא יותר מ-8 שעות (מתוך 7 הימים) מזמן ההכנה ועד סיום מתן העירוי.~~
~~או~~
~~בקירור בטמפרטורה של 2°C-8°C ומוגן מאור לפרק זמן של עד 7 ימים מרגע ההכנה ועד לסיום המתן.~~
- אין להקפיא או לנער.
- אין להשליך תרופות לביוב או לאשפה. שאל את הרוקח כיצד להשמיד תרופות שאינן בשימוש. אמצעים אלו יעזרו להגן על הסביבה.

...

מידע לצוות הרפואי
معلومات للطاقم الطبي
Information for Healthcare professionals

Preparation and Administration

...

OPDIVO may be administered either without dilution or after dilution as described below.

...

- After preparation of infusion:
  Chemical and physical in-use stability from the time of preparation has been demonstrated as follows (times are inclusive of the administration period):

Infusion preparation	Chemical and physical in-use stability	
	Storage at 2ºC to 8ºC protected from light	Storage at room temperature (≤ 25°C) and room light
Undiluted or diluted with sodium chloride 9 mg/mL (0.9%) solution for injection	30 days	24 hours (of total 30 days storage)
Diluted with 50 mg/mL (5%) glucose solution for injection	7 days	8 hours (of total 7 days storage)

From a microbiological point of view the prepared solution for infusion, regardless of the diluent, 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 7 days at 2°C to 8°C or 8 hours (of the total 7 days of storage) at room temperature (≤ 25°C). Aseptic handling should be ensured during the preparation of infusion.

...

- ~~After preparation, store the diluted solution either:~~

- ~~at room temperature and room light for no more than 8 hours from the time of preparation to end of the infusion. Discard diluted solution if not used within 8 hours from the time of preparation; or~~
- ~~under refrigeration at 2°C to 8°C and protected from light for no more than 7 days from the time of preparation to end of infusion. Discard diluted solution if not used within 7 days from the time of preparation.~~

...

Administration

- Administer the infusion~~, after dilution,~~ over 30 minutes or 60 minutes depending on the dose through an intravenous line containing a sterile, non-pyrogenic, low protein binding in-line filter (pore size of 0.2 micrometer to 1.2 micrometer).
- Administer OPDIVO in combination with other therapeutic agents as follows:

Combination Therapy	
Ipilimumab	Administer OPDIVO first, followed by the other therapeutic agent(s).
Platinum-Doublet Chemotherapy	
Ipilimumab and Platinum-Doublet Chemotherapy	
Fluoropyrimidine- and Platinum-Containing Chemotherapy	
Doxorubicin, Vinblastine, and Dacarbazine (AVD)	Administer OPDIVO last.

  - ~~With ipilimumab: administer OPDIVO first followed by ipilimumab on the same day.~~
  - ~~With platinum-doublet chemotherapy: administer OPDIVO first followed by platinum doublet chemotherapy on the same day.~~
  - ~~With ipilimumab and platinum-doublet chemotherapy: administer OPDIVO first followed by ipilimumab and then platinum-doublet chemotherapy on the same day.~~
  - ~~With fluoropyrimidine- and platinum-containing chemotherapy: administer OPDIVO first followed by fluoropyrimidine- and platinum-containing chemotherapy on the same day.~~

...