

ספטמבר 2023

Bavencio[®] (Avelumab), concentrate for solution for infusion vial

רופא/ה, רוקח/ת וצוות רפואי נכבדים,

אנו מבקשים להודיעכם כי חיי מדף לאחר מיהול בעלון לרופא של התכשיר Bavencio עודכנו.

ההתוויות המאושרות:

Metastatic Merkel Cell Carcinoma

Bavencio is indicated for the treatment of adult patients with metastatic Merkel cell carcinoma (MCC).

Locally Advanced or Metastatic Urothelial Carcinoma

First-Line Maintenance Treatment of Urothelial Carcinoma

Bavencio is indicated for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy.

Previously-Treated Urothelial Carcinoma

Bavencio is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) 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.

Advanced Renal Cell Carcinoma

Bavencio in combination with axitinib is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

השינויים בעלון לרופא הינם (טקסט שנוסף מופיע עם קו תחתון, טקסט שנמחק מופיע עם קו חוצה):

6.3 Shelf life

...

After preparation of infusion

Chemical and physical in-use stability of the diluted solution has been demonstrated ~~for 24 hours at room temperature and room light~~ as follows:



Merck Serono Ltd.

18 Kishon St.
Yavne, Israel 81220
Tel: +972 8 9382610
Fax: +972 8 9403152
office.israel@merckgroup.com

www.merckserono.co.il

<u>Infusion solution</u>	<u>Storage at 2°C to 8°C protected from light</u>	<u>Storage at 20°C to 25°C and room light</u>
<u>Sodium chloride 9 mg/mL (0.9%) solution for injection</u>	<u>96 hours</u>	<u>72 hours</u>
<u>Sodium chloride 4.5 mg/mL (0.45%) solution for injection</u>	<u>24 hours</u>	<u>24 hours</u>

From a microbiological point of view, ~~the diluted solution should be infused immediately, unless the method of dilution precludes the risk of microbial contamination, has taken place in controlled and validated aseptic conditions.~~ the diluted solution should be infused immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user, ~~and must not be longer than a total of 24 hours under refrigerated conditions (2°C to 8°C) or up to 8 hours at room temperature (20°C to 25°C). If refrigerated, allow the vial and/or intravenous bags to come to room temperature prior to use.~~

למידע המלא יש לעיין בעלון לרופא כפי שאושר על ידי משרד הבריאות.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום
מרק סרונו בע"מ, רח' הקישון 18, יבנה 81220, טל' 09-9510737

בברכה,

אורית פוקס
רוקחת ממונה