

מרץ 2024

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

רופא/ה, הוקח/ת וצוות רפואי נכבדים,

אנו מבקשים להודיעכם העלון לרופא של התכשיר Bavencio עודכן עם עדכון בטיחות.

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):

4.4 Special warnings and precautions for use

[...]

Immune-related adverse reactions

[...]

In patients with pre-existing autoimmune disease (AID), data from observational studies suggest that the risk of immune-related adverse reactions following immune-checkpoint inhibitor therapy



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may be increased as compared with the risk in patients without pre-existing AID. In addition, flares of the underlying AID were frequent, but the majority were mild and manageable.

[...]

Other immune-related adverse reactions

Other clinically important immune-related adverse reactions were reported in less than 1% of patients: myositis, hypopituitarism, uveitis, myasthenia gravis, myasthenic syndrome, cystitis noninfective, **sarcoidosis**, and Guillain-Barré syndrome (see section 4.8).

[...]

Patients excluded from clinical studies

[...]

Avelumab should be used with caution in these populations after careful consideration of the potential benefit/risk on an individual basis.

4.8 Undesirable effects

[...]

Table 2: Adverse reactions in patients treated with avelumab as monotherapy

[...]

Frequency	Adverse reactions
Immune system disorders	
Uncommon	Hypersensitivity, drug hypersensitivity, sarcoidosis**

[...]

**** Sarcoidosis was observed in clinical trials in patients receiving avelumab in combination with platinum-based chemotherapy**

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
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בברכה,

אורית פוקס

חוקחת ממונה