יוני 2022

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

רופא/ה, רוקח/ת וצוות רפואי נכבדים,

אנו מבקשים להודיעכם כי העלון לרופא של התכשיר Bavencio עודכן.

<u>ההתוויות המאושרות:</u>

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
<u>First-Line Maintenance Treatment of Urothelial Carcinoma</u>
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.

<u>Previously-Treated Urothelial Carcinoma</u>
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).

<u>ההחמרות בעלון לרופא הינן</u> (טקסט שנוסף מודגש בצהוב, טקסט שנמחק מופיע עם ~~קו חוצה~~):

Posology
Treatment modification
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Treatment-related adverse reaction	**Severity***	**Treatment modification**
Skin reactions	Grade 3 rash	Withhold until adverse reactions recover to Grade 0-1

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

	Grade 4 or recurrent Grade 3 rash or confirmed Stevens–Johnson syndrome (SJS) or Toxic epidermal necrolysis (TEN)	Permanently discontinue

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4.4 Special warnings and precautions for use

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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, and Guillain-Barré syndrome (see section 4.8).

For suspected immune-related adverse reactions, ensure adequate evaluation to confirm aetiology or to rule out other causes. Based on the severity of the adverse reaction, avelumab should be withheld and corticosteroids to be administered. Avelumab should be resumed when the immune-related adverse reaction returns to Grade 1 or less following corticosteroid taper. Avelumab should be permanently discontinued for any Grade 3 immune-related adverse reaction that recurs and for Grade 4 immune-related adverse reaction (see section 4.2).

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4.8 Undesirable effects

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

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Frequency	**Adverse reactions**
Renal and urinary disorders	
Uncommon	Renal failure*, nephritis*
Rare	Tubulo-interstitial nephritis*, cystitis noninfective*

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* Immune-related adverse reaction based on medical review

† Adverse reactions occurred in estimated 4,000 patients exposed to avelumab monotherapy beyond the pooled analysis.

§ Reaction only observed from study EMR 100070-003 (Part B) after the data cut-off of the pooled analysis, hence frequency estimated

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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