

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

רופא/ה, רוקח/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, החמרות **מודגשות בצהוב**, טקסט שנמחק מופיע עם קו חוצה):

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

(...)

Excipients with known effect

This medicinal product contains 5 mg of polysorbate 20 per vial.

(...)

4.4 Special warnings and precautions for use

(...)

Other immune-mediated adverse reactions

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

(...)



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Polysorbate content

This medicinal product contains 5 mg of polysorbate 20 per vial. Polysorbates may cause allergic reactions. This should be taken into consideration for treating patients with Bavencio.

(...)

4.8 Undesirable effects

(...)

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

| Frequency | Adverse reactions |
|---|--|
| Immune system disorders | |
| Very common | Infusion-related reaction [#] |
| Common | Hypersensitivity, drug hypersensitivity, sarcoidosis** |
| Rare | Anaphylactic reaction, Type I hypersensitivity |
| Gastrointestinal disorders | |
| Very common | Nausea, diarrhoea, constipation, vomiting, abdominal pain |
| Common | Dry mouth |
| Uncommon | Ileus, colitis* |
| Rare | Pancreatitis*, autoimmune colitis*, enterocolitis*, autoimmune pancreatitis*, enteritis*, proctitis* |
| Not known | Gastritis* |
| Injury, poisoning and procedural complications | |
| Very common | Infusion related reaction |

[#] Including cytokine release syndrome with frequency uncommon

(...)

Table 3: Adverse reactions in patients treated with avelumab in combination with axitinib

| Frequency | Adverse reactions |
|---|---|
| Immune system disorders | |
| Very common | Infusion-related reaction [#] |
| Common | Hypersensitivity |
| Gastrointestinal disorders | |
| Very common | Diarrhoea, nausea, constipation, vomiting, abdominal pain |
| Common | Dry mouth, colitis* |
| Uncommon | Autoimmune colitis*, autoimmune pancreatitis*, enterocolitis*, ileus, pancreatitis necrotizing* |
| Not known | Gastritis* |
| Injury, poisoning and procedural complications | |
| Very common | Infusion related reaction |

[#] Including cytokine release syndrome with frequency not known

(...)

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

