BAVENCIO® avelumab Injection 20 mg/mL

PRODUCT INFORMATION

Description
200 mg/10 mL (20 mg/mL) solution in a single-dose vial

Quantity
One vial per carton

Units Per Case
24

NDC
44087-3535-01

Global Trade Identification Numbers
00344087353513
20344087353517 (case)

UPC Code
3 44087 35351 3

STORAGE AND HANDLING REQUIREMENTS

Store refrigerated at 36°F to 46°F (2°C to 8°C) in original package to protect from light.

After preparation, store diluted BAVENCIO (avelumab) solution either:

- At room temperature up to 77°F (25°C) for no more than 4 hours from the time of dilution
- Under refrigeration at 36°F to 46°F (2°C to 8°C) for no more than 24 hours from the time of dilution. If refrigerated, allow the diluted solution to come to room temperature prior to administration

Do not freeze or shake diluted solution.

SUPPLIED AND MARKETED BY

EMD Serono, Inc. and Pfizer Inc.
www.emdserono.com | www.pfizer.com | www.BAVENCIO.com

PRODUCT EXPIRATION

The expiration date is printed on each box and vial label.

CUSTOMER SERVICE

1-888-398-4567 or
us.customerservice@emdserono.com.

For information and instructions regarding product ordering or returns, please contact your specialty distributor or Customer Service at 1-888-398-4567.

REIMBURSEMENT SUPPORT INFORMATION

CoverOne®: 844-8COVER1 (844-826-8371)
or www.CoverOne.com.

CHECK MY MEDS™ PROGRAM

At EMD Serono, your safety is our first priority. That's why we created **Check My Meds**, a smartphone application to help you and your patients verify the authenticity of EMD Serono medications.

To learn more, visit http://www.emdserono.com/en/therapies/check_my_meds/check_my_meds.html.

Check My Meds is now available for download on iOS and Android products.

INDICATIONS

BAVENCIO is indicated for the treatment of:

- Adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC)
- Patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see the Important Safety Information on page 3. Click for the full Prescribing Information or visit BAVENCIO.com.

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SPECIALTY DISTRIBUTION PARTNERS

For your convenience, we are providing the following list of BAVENCIO distributors:

McKesson Plasma and Biologics
2615 Medical Center Parkway, Ste 1580,
Murfreesboro, TN 37129
Phone: 877-625-2566
Fax: 888-752-7626
Email: mpborders@mckesson.com
Online: https://connect.mckesson.com
BAVENCIO item #3638475

McKesson Specialty Health
401 Mason Road, La Vergne, TN 37086
Phone: 800-482-6700
Fax: 800-289-9298
Email: msh-customercare@mckesson.com
BAVENCIO material #5006810 / BAVENCIO catalog #003-110

ASD Healthcare
3101 Gaylord Parkway, Frisco, TX 75034
Phone: 800-746-6273 (On Call for Emergency: 365/24/7)
Fax: 800-547-9413
Email: asd.customerservice@asdhealthcare.com
BAVENCIO item #48448

Oncology Supply
2801 Horace Shepard Drive, Dothan, AL 36303
Phone: 800-633-7555
Email: customerservice@oncologysupply.com
BAVENCIO item: #48448

Cardinal Health Specialty Solutions
15 Ingram Boulevard, LaVergne, TN 37086
Hospitals: 866-677-4844
Physician office: 866-300-3838
BAVENCIO order #:
- Clinic 5307574
- Acute (hospital) 5325915

Biologics Specialty Pharmacy
11800 Weston Parkway, Cary, NC 27513
Phone: 1.800.850.4306 – Option 2
Fax: 1.800.823.4506
Hours: 8AM-8PM EST Mon-Fri, 24/7 on-call service
www.biologicsinc.com

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IMPORTANT SAFETY INFORMATION FOR BAVENCIO® (avelumab) Injection 20 mg/mL

BAVENCIO can cause **immune-mediated pneumonitis**, including fatal cases. Monitor patients for signs and symptoms of pneumonitis and evaluate suspected cases with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold BAVENCIO for moderate (Grade 2) and permanently discontinue for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis. Pneumonitis occurred in 1.2% (21/1738) of patients, including one (0.1%) patient with Grade 5, one (0.1%) with Grade 4, and five (0.3%) with Grade 3.

BAVENCIO can cause **immune-mediated hepatitis**, including fatal cases. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater hepatitis. Withhold BAVENCIO for moderate (Grade 2) immune-mediated hepatitis until resolution and permanently discontinue for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hepatitis. Immune-mediated hepatitis was reported in 0.9% (16/1738) of patients, including two (0.1%) patients with Grade 5, and 11 (0.6%) with Grade 3.

BAVENCIO can cause **immune-mediated colitis**. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold BAVENCIO until resolution for moderate or severe (Grade 2 or 3) colitis and permanently discontinue for life-threatening (Grade 4) or recurrent (Grade 3) colitis upon re-initiation of BAVENCIO. Immune-mediated colitis occurred in 1.5% (26/1738) of patients, including seven (0.4%) with Grade 3.

BAVENCIO can cause **immune-mediated endocrinopathies**, including adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus.

Monitor patients for signs and symptoms of **adrenal insufficiency** during and after treatment, and administer corticosteroids as appropriate. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Adrenal insufficiency was reported in 0.5% (8/1738) of patients, including one (0.1%) with Grade 3.

Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation. Manage hypothyroidism with hormone replacement therapy and hyperthyroidism with medical management. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) thyroid disorders. Thyroid disorders, including hypothyroidism, hyperthyroidism, and thyroiditis, were reported in 6% (98/1738) of patients, including three (0.2%) with Grade 3.

Type 1 diabetes mellitus including diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Withhold BAVENCIO and administer anti-hyperglycemics or insulin in patients with severe or life-threatening (Grade ≥ 3) hyperglycemia, and resume treatment when metabolic control is achieved. Type 1 diabetes mellitus without an alternative etiology occurred in 0.1% (2/1738) of patients, including two cases of Grade 3 hyperglycemia.

BAVENCIO can cause **immune-mediated nephritis and renal dysfunction**. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater nephritis. Withhold BAVENCIO for moderate (Grade 2) or severe (Grade 3) nephritis until resolution to Grade 1 or lower. Permanently discontinue BAVENCIO for life-threatening (Grade 4) nephritis. Immune-mediated nephritis occurred in 0.1% (1/1738) of patients.

BAVENCIO can result in **other severe and fatal immune-mediated adverse reactions** involving any organ system during treatment or after treatment discontinuation. For suspected immune-mediated adverse reactions, evaluate to confirm or rule out an immune-mediated adverse reaction and to exclude other causes. Depending on the severity of the adverse reaction, withhold or permanently discontinue BAVENCIO, administer high-dose corticosteroids, and initiate hormone replacement therapy, if appropriate. Resume BAVENCIO when the immune-mediated adverse reaction remains at Grade 1 or lower following a corticosteroid taper. Permanently discontinue BAVENCIO for any severe (Grade 3) immune-mediated adverse reaction that recurs and for any life-threatening (Grade 4) immune-mediated adverse reaction. The following clinically significant immune-mediated adverse reactions occurred in less than 1% of 1738 patients treated with BAVENCIO: myocarditis with fatal cases, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, and systemic inflammatory response.

BAVENCIO can cause severe (Grade 3) or life-threatening (Grade 4) **infusion-related reactions**. Patients should be premedicated with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent doses based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. Permanently discontinue BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Infusion-related reactions occurred in 25% (439/1738) of patients, including three (0.2%) patients with Grade 4 and nine (0.5%) with Grade 3.

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least 1 month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least 1 month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, ≥ 20%) in patients with **metastatic Merkel cell carcinoma (MCC)** were fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reaction (22%), rash (22%), decreased appetite (20%), and peripheral edema (20%).

Selected treatment-emergent laboratory abnormalities (all grades, ≥ 20%) in patients with **metastatic MCC** were lymphopenia (49%), anemia (35%), increased aspartate aminotransferase (34%), thrombocytopenia (27%), and increased alanine aminotransferase (20%).

The most common adverse reactions (all grades, ≥ 20%) in patients with **locally advanced or metastatic urothelial carcinoma (UC)** were fatigue (41%), infusion-related reaction (30%), musculoskeletal pain (25%), nausea (24%), decreased appetite/hypophagia (21%), and urinary tract infection (21%).

Selected laboratory abnormalities (Grades 3-4, ≥ 3%) in patients with **locally advanced or metastatic UC** were hyponatremia (16%), increased gamma-glutamyltransferase (12%), lymphopenia (11%), hyperglycemia (9%), increased alkaline phosphatase (7%), anemia (6%), increased lipase (6%), hyperkalemia (3%), and increased aspartate aminotransferase (3%).

Click for the full Prescribing Information or visit BAVENCIO.com.

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