Abridged Prescribing Information

Abevmy® (Bevacizumab)

Composition: Each Abevmy® 100 mg in 4 mL vial contains 100 mg and each Abevmy® 400 mg in 16 mL vial contains 400 mg of bevacizumab concentrate for solution for IV infusion. **Indications:** Metastatic carcinoma of the colon or rectum: Treatment of adult patients with metastatic carcinoma of the colon or rectum in combination with fluoropyrimidine-based chemotherapy. Non-squamous Non-small Cell Lung Cancer (NSCLC): First-line treatment of non-squamous NSCLC in combination with platinum-based chemotherapy and for first-line treatment of non-squamous NSCLC with EGFR activating mutations in combination with erlotinib. Glioblastoma: As a single agent for adult patients with progressive disease following prior therapy. Advanced and/or metastatic renal cell cancer: First-line treatment in combination with interferon alpha-2a of adult patients with advanced and/or metastatic renal cell cancer. Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Front-line treatment in combination with carboplatin and paclitaxel of adult patients. Treatment in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by use as a single agent for adult patients with platinum-sensitive recurrent cancer who have not received prior therapy with bevacizumab, other VEGF inhibitors, or VEGF receptor–targeted agents. Treatment in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin of adult patients with platinum-resistant recurrent cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab, other VEGF inhibitors, or VEGF receptor–targeted agents. Metastatic carcinoma of the cervix: Treatment of persistent, recurrent, or metastatic carcinoma of the cervix in adult patients, in combination with paclitaxel and cisplatin; or, alternatively, paclitaxel and topotecan for those who cannot receive platinum therapy. **Dosage and Administration:** Deliver the initial bevacizumab dose as an IV infusion, over 90 minutes. The second infusion can be administered over 60 minutes, if the first is well tolerated; and subsequent infusions can be administered over 30 minutes, if infusion over 60 minutes is tolerated. Metastatic Colorectal Cancer (mCRC): The recommended dose of bevacizumab, administered as an IV, is either 5 mg/kg or 10 mg/kg of body weight given once every 2 weeks or 7.5 mg/kg or 15 mg/kg of body weight given once every 3 weeks. NSCLC: 15 mg/kg of body weight given once every 3 weeks. Glioblastoma: 10 mg/kg of body weight given once every 2 weeks or 7.5 mg/kg or 15 mg/kg of body weight given once every 3 weeks. Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer: Front line: 15 mg/kg of body weight given once every 3 weeks up to six cycles of treatment; thereafter, continue bevacizumab as a single agent for 15 months or until disease progression, whichever occurs earlier. For recurrent ovarian cancer 15 mg/kg of body weight given once every 3 weeks. Metastatic carcinoma of the cervix: 15 mg/kg of body weight given once every 3 weeks. For majority of the indications, continue bevacizumab treatment until progression of the underlying disease or unacceptable toxicity. **Special populations:** Pregnancy: Female patients of reproductive potential should be advised to use effective contraception during treatment with bevacizumab and for 6 months following the last dose of bevacizumab. Lactation: There is no data to indicate whether bevacizumab is present in human milk; has effects on the breast fed infant; or effects on milk production. Geriatric patients: Use in patients aged ≥65 years given bevacizumab, the following severe adverse events occurred more frequently (≥2%) than in younger patients: asthenia, sepsis, deep thrombophlebitis, hypertension, hypotension, myocardial infarction, congestive heart failure, diarrhea, constipation, anorexia, leukopenia, anemia, dehydration, hypokalemia, hypernatremia, arterial thromboembolic reactions, including cerebrovascular accidents, transient ischemic attacks and myocardial infarctions; grade 3-4 thrombocytopenia; and all grade neutropenia, nausea, headache and fatigue. Bevacizumab had a similar effect on overall survival in elderly patients and younger patients. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients, hypersensitivity to Chinese Hamster Ovary (CHO) cell products or other

recombinant human or humanized antibodies. **Warnings and Precautions:** Perforations and fistulae: There is increased risk of developing gastrointestinal perforation, gallbladder perforation. Gastrointestinal-vaginal fistulae: Prior radiation is a major risk factor for the development of GI-vaginal fistulae. Bevacizumab treatment may increase the risk of patients developing non-gastrointestinal fistulae. Bevacizumab should be permanently discontinued in any grade 4 fistula. Wound Healing Complications: Bevacizumab may have adverse effects on wound healing. Serious complications including anastomotic complications, have occurred; with fatal outcomes. Do not start therapy for atleast 28 days after major surgery or till the surgical wound has healed completely. If a patient experiences wound healing complications, withhold bevacizumab till the wound is fully healed. Patients undergoing elective surgery should have therapy withheld. Hypertension: Bevacizumab-treated patients showed a higher incidence of hypertension. Before bevacizumab treatment is initiated, pre-existing hypertension should be properly controlled. Posterior Reversible Encephalopathy Syndrome (PRES): In rare cases, bevacizumab-treated patients have developed signs and symptoms consistent with the rare neurologic disorder. Proteinurea: Patients who have had hypertension may have a higher risk of proteinuria if treated with bevacizumab. Proteinuria should be monitored by appropriate urine analysis, preferably by dipstick, before starting bevacizumab treatment, and during the treatment. If patients develop nephritic syndrome permanently discontinue bevacizumab treatment. Arterial thromboembolism: Arterial thromboembolic reactions such as Cerebrovascular Accidents (CVAs), transient ischemic attacks and myocardial infarctions had a higher incidence in patients treated with bevacizumab in combination with chemotherapy, than in patients receiving chemotherapy alone. **Adverse Reactions:** The most common adverse reactions (those with incidence >10% and at least twice as frequent as in the control arm) are epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain and exfoliative dermatitis. Though some of the adverse reactions are commonly seen with chemotherapy, bevacizumab may exacerbate these reactions when combined with chemotherapeutic agents. Hypertension, fatigue or asthenia, diarrhea and abdominal pain were the most frequently observed adverse reactions in patients. **Overdose:** 20 mg/kg IV is the highest dose tested in humans, and was associated with headache in 9 of 16 patients and with severe headache in 3 of 16 patients. **Storage:** Store vials at 2°C–8°C. Keep out of reach of children. Keep vial in the outer carton in order to protect from light.

Dated: 6thOctober 2017

For more details and information, please refer the pack insert or full prescribing information