

21

WARNING



STEP, TOWARDS VICTORY WITH VECTIBIX®

WHAT'S BEHIND MVASI[®] MAKES THE DIFFERENCE

TARGETED SOLUTIONS FOR YOUR MCRC PATIENTS^{1,2}

Vectibix[®] is indicated for the treatment of adult patients with WT RAS metastatic colorectal cancer in the first-line in combination with FOLFOX or FOLFIRI²

MVASI[®] in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of patients with metastatic carcinoma of the colon or rectum¹

Abbreviations:

EGFR=epidermal growth factor receptor; FOLFIRI=Leucovorin, fluorouracil, and irinotecan; FOLFOX=Leucovorin, fluorouracil, and oxaliplatin; mCRC=metastatic colorectal cancer; RAS=rat sarcoma virus gene; VEGF=vascular endothelial growth factor; WT=wild type

References:

1. MVASI (bevacizumab) Singapore Prescribing Information **2.** Vectibix (panitumumab) Singapore Prescribing Information

Please review full product information before prescribing

ABBREVIATED PRODUCT INFORMATION

Vectibix Concentrate for Solution for Infusion 100 mg/vial

INDICATIONS: Treatment of adult patients with wild-type RAS metastatic colorectal cancer (mCRC) (see full PI Special – Warnings & Precautions: RAS tumour genetic marker testing): in first-line therapy in combination with FOLFOX or FOLFIRI; in second-line therapy in combination with FOLFIRI for patients who have received first-line fluoropyrimidine-based chemotherapy (excluding irinotecan); as monotherapy after the failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. CONTRAINDICATIONS: History of severe or life-threatening hypersensitivity to panitumumab or to any of the excipients. Patients with interstitial pneumonitis or pulmonary fibrosis. Combination of Vectibix with oxaliplatin-containing chemotherapy in patients with mutant RAS mCRC or for whom RAS mCRC status is unknown (see full PI Special - Warnings and Precautions). **PRECAUTIONS:** Assess risk-benefit prior to initiation in patients with ECOG 2 performance status. Monitor dermatologic reactions and soft tissue toxicity (severe or life-threatening reactions - modify, discontinue or withhold dose). Patients should wear sunscreen and a hat and limit sun exposure. Severe or life-threatening infusion reactions - Vectibix should be permanently discontinued. Hypersensitivity reactions. Acute onset/worsening pulmonary toxicity - interrupt therapy and investigate symptoms. Monitor patients for the development of venous thrombolic events. Avoid combination with IFL chemotherapy or bevacizumab-containing chemotherapy. Acute renal failure has been observed in patients who develop severe diarrhoea and dehydration. Monitor for keratitis or ulcerative keratitis, which may lead to corneal perforation. Monitor for hypomagnesaemia and hypocalcaemia prior, during and 8 weeks after therapy - replete electrolytes as appropriate. Acute renal failure - patients who experience severe diarrhoea should be instructed to consult a healthcare professional urgently. Administration of Vectibix in combination with IFL should be avoided. Vectibix should not be administered in combination with bevacizumab containing chemotherapy. Ocular toxicities - Serious cases of keratitis and ulcerative keratitis have been reported, if ulcerative keratitis is diagnosed, treatment with Vectibix should be interrupted or discontinued. **INTERACTION:** Should not administer in combination with IFL chemotherapy OR bevacizumab containing chemotherapy. PREGNANCY & LACTATION: Vectibix has the potential to cause foetal harm when administered to pregnant women. May impair fertility in women. Do not breast-feed during and for 2 months after the last dose of Vectibix. Paediatric safety and efficacy not established. **ADVERSE REACTIONS:** Skin and sub-cutaneous disorders including skin necrosis, gastrointestinal disorders, fatigue, infusion reactions and other hypersensitivity even >24hr after infusion, pulmonary embolism, electrolyte depletion, dehydration, keratitis and/or ulcerative keratitis, which may lead to corneal perforation. **DOSAGE AND ADMINISTRATION:** 6 mg/kg of body weight by IV infusion once every 2 weeks until disease progression. Evidence of wild-type RAS status is required before initiating treatment. Mutational status should be determined by an experienced laboratory using validated test methods for detection of KRAS (exons 2, 3 and 4) and NRAS (exons 2, 3 and 4) mutations.

Based on approved PI dated 04 May 2022

MVASI ABBREVIATED PRODUCT INFORMATION

INDICATION: METASTATIC CARCINOMA OF THE COLON OR RECTUM (MCRC) MVASI combination with fluoropyrimidine-based chemotherapy indicated for patients with metastatic carcinoma of the colon or rectum. METASTATIC BREAST CANCER (mBC) MVASI combination with paclitaxel indicated for patients who have not received chemotherapy for metastatic HER2-negative breast cancer. MVASI combination with capecitabine indicated for first-line treatment with HER2-negative metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate. Patients who have received taxane and anthracycline-containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with MVASI in combination with capecitabine. The effectiveness of MVASI in metastatic breast cancer (mBC) is based on an improvement in progression-free survival. NON-SMALL CELL LUNG CANCER (NSCLC) MVASI with carboplatin and paclitaxel, indicated for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous, non-small cell lung cancer. MVASI with erlotinib, indicated for first-line treatment of patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations. MALIGNANT GLIOMA (WHO GRADE IV) - GLIOBLASTOMA MVASI, as a single agent for the treatment of patients with glioblastoma after relapse or disease progression following prior therapy. ADVANCED **AND/OR METASTATIC RENAL CELL CANCER (mRCC)** MVASI with interferon alfa-2a for first-line treatment of patients with advance and/or metastatic renal cell cancer. **EPITHELIAL OVARIAN, FALLOPIAN TUBE AND PRIMARY PERITONEAL CANCER** MVASI, with carboplatin and paclitaxel is for the front-line treatment of advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. MVASI, with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel is for the treatment of patients with recurrent, platinum-sensitive, epithelial ovarian, fallopian tube, or primary peritoneal cancer who have not received prior bevacizumab or other VEGF-targeted angiogenesis inhibitors. MVASI with paclitaxel, topotecan or pegylated liposomal doxorubicin for the treatment of patients with recurrent, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor-targeted agents. **CERVICAL CANCER** MVASI in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix. CONTRAINDICATIONS: known hypersensitivity to any components of Mvasi, known hypersensitivity to Chinese hamster ovary cell products or other recombinant human or humanised antibodies and pregnancy WARNINGS AND PRECAUTIONS: Gastrointestinal perforations and fistulae, non-GI fistulae, hypertension, wound healing, arterial thromboembolism, venous thromboembolism, hemorrhage, severe eye infections following compounding for unapproved intravitreal use, posterior reversible encephalopathy syndrome, proteinuria, pulmonary haemorrhage/haemoptysis, aneurysms and artery dissections, ovarian failure/fertility, congestive heart failure/cardiomyopathy, hypersensitivity reactions, infusion reactions, neutropenia and osteonecrosis of the jaw. INTERACTIONS: Risk of microangiopathic haemolytic anaemia with sunitinib malate. May increase rates of severe neutropenia, febrile neutropenia, or infection with or without severe neutropenia with platinum- or taxane-based therapies in the treatment of NSCLC and mBC. ADVERSE REACTIONS: GI and gall bladder perforation, ileus, intestinal obstruction, hepatobiliary disorder, GI disorder, arterial thromboembolism, hypertension, fatigue or asthenia, pyrexia, pain, mucosal inflammation, abdominal pain, diarrhoea, constipation, nausea, vomiting, anorexia, febrile neutropenia, leucopenia, neutropenia, thrombocytopenia, peripheral sensory neuropathy, dysarthria, headache, dysgeusia, eye disorder, increased lacrimation, venous thromboembolism, dyspnoea, rhinitis, rectal haemorrhage, stomatitis, exfoliative dermatitis, skin discolouration, dry skin, arthralgia, proteinuria, ovarian failure, sepsis, abscess, infection, UTI, anaemia, hypersensitivity infusion reaction, dehydration, CVA, somnolence, syncope, CHF, supraventricular tachycardia, DVT, pulmonary embolism, hypoxia, epistaxis, dysphonia, palmar-plantar erythrodysaesthesia syndrome, fistula, myalgia, muscular weakness, lethargy. DOSAGE & ADMINISTRATION: Mvasi is for intravenous use. METASTATIC CARCINOMA OF THE COLON OR RECTUM (mCRC) First-line: 5 mg/kg once every 2 weeks or 7.5 mg/kg once every 3 weeks. Second-line: 10 mg/kg every 2 weeks with FOLFOX-4.5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks combination with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin. METASTATIC BREAST CANCER (mBC) 10 mg/kg once every 2 weeks with paclitaxel or 15 mg/kg once every 3 weeks with capecitabine. NON-SMALL CELL LUNG CANCER (NSCLC) First-line: 15 mg/kg every 3 weeks in addition to platinum-based chemotherapy for up to 6 cycles of treatment followed by MVASI as a single agent until disease progression. Or 15 mg/kg every 3 weeks in addition to erlotinib. MALIGNANT GLIOMA - GLIOBLASTOMA 10 mg/kg once every 2 weeks. ADVANCED AND/OR METASTATIC RENAL CELL CANCER (mRCC) 10 mg/kg once every 2 weeks. EPITHELIAL OVARIAN, FALLOPIAN TUBE AND PRIMARY PERITONEAL **CANCER** Front-line: 15 mg/kg once every 3 weeks with carboplatin and paclitaxel for up to 6 cycles of treatment followed by MVASI single agent until disease progression or for a maximum of 15 months or until unacceptable toxicity. Recurrent Disease: Platinum-sensitive: 15 mg/kg once every 3 weeks with carboplatin and paclitaxel for 6 cycles and up to 8 cycles followed by MVASI as single agent until disease progression. Or, 15 mg/kg every 3 weeks with carboplatin and gemcitabine for 6 cycles and up to 10 cycles followed by continued use of MVASI as single agent until disease progression. Platinum-resistant: 10 mg/kg once every 2 weeks with - paclitaxel, topotecan (given weekly) or pegylated liposomal doxorubicin. Or, 15 mg/kg every 3 weeks with topotecan on days 1 - 5, every 3 weeks, continued until disease progression. CERVICAL CANCER 15 mg/kg every 3 weeks with paclitaxel and cisplatin, or paclitaxel and topotecan, to be continued until progression of the underlying disease.

Based on approved PI dated 27 July 2022 Amgen internal reference: SGMVAPI03

For Healthcare Professionals only. All images are for illustration purpose only. Please refer to the full prescribing information prior to administration, which is available upon request. For further information, please contact Medical Information at 800 616 7094 or email: medinfo.JAPAC@amgen.com



Amgen Biotechnology Singapore Pte Ltd 3 Fraser Street, #15-26/27, DUO Tower, Singapore 189352 SG-03348-MVA-2022-Sep