NOVARTIS

VOTRIENT® (pazopanib)
200 mg and 400 mg Film-coated tablets

Basic Succinct Statement (BSS)

CODE: BSS RD 25 Nov 19; APPR 30 Mar 20

VOTRIENT®

Important note: Before prescribing, consult full prescribing information.

Presentation: Film-coated tablet: contains 200 or 400 mg pazopanib.

Indications: ♦Treatment of advanced and/or metastatic renal cell carcinoma (RCC). ♦Treatment of patients with advanced Soft Tissue Sarcoma (STS) who have received prior chemotherapy.

Dosage and administration: ♦The recommended maximum daily dose is 800 mg.

Special populations: ♦Children: Safety and efficacy not established. **♦Elderly (>65 years):** No dose adjustment required. **♦Renal impairment:** No dose adjustment required in patients with creatinine clearance ≥30 mL/minutes. Not recommended in patients with severe renal impairment or in patients undergoing peritoneal dialysis or hemodialysis. **♦Hepatic impairment:** Mild: No dose adjustment required. Moderate: Max 200 mg/day. Severe: Not recommended.

Contraindications: ♦ In patients with hypersensitivity to any of the ingredients.

Warnings and precautions: ♦Hepatic effects: Monitor liver enzymes. Concomitant use of Votrient and simvastatin increases the risk of ALT elevations. **♦Hypertension**: Discontinue in case of hypertensive crisis or if hypertension is severe and persists despite anti-hypertensive therapy and Votrient dose reduction. **♦Posterior reversible encephalopathy syndrome (PRES)/Reversible posterior leukoencephalopathy syndrome (RPLS)**: Permanently discontinue Votrient in patients developing PRES/RPLS **♦Interstitial lung disease (ILD)/Pneumonitis**: Discontinue Votrient in patients developing ILD or pneumonitis. **♦Cardiac dysfunction**: Monitoring of blood pressure and clinical signs or symptoms of congestive heart failure. Baseline and periodic evaluation of left ventricular ejection fraction (LVEF) in patients at risk of cardiac dysfunction. **♦QT prolongation and torsade de pointes**: Caution in patients with a history of QT interval prolongation, patients taking antiarrhythmics or drugs that prolong QT interval, or those with relevant pre-existing cardiac disease. Baseline and periodic monitoring of electrocardiograms and electrolytes. **♦Arterial/Venous thrombotic events**: Caution in patients at increased risk of thrombotic events or with history of thrombotic events. **♦Thrombotic microangiopathy (TMA)**: Discontinue permanently in patients developing TMA. **♦Hemorrhagic events**: Caution in patients with significant risk of hemorrhage. **♦Gastrointestinal perforations and fistula**: Use with caution in patients at risk for gastrointestinal (GI) perforation or fistula. **♦Wound healing**: Discontinue in patients with wound dehiscence. **♦Hypothyroidism**: Proactive monitoring of thyroid function. **♦Proteinuria**: Baseline and periodic urinalyses recommended and monitor for worsening proteinuria. Discontinue if patient develops nephrotic syndrome. **♦Tumor lysis syndrome (TLS):** Preventative measures, close monitoring and treatment as clinically indicated in patients at risk for TLS. ♦ **Infections**: Cases of serious infections reported. **♦Combination with other systemic anti-cancer therapies**: Not indicated for use in combination with other anti-cancer agents. **♦Juvenile animal toxicity**: Not recommended in patients below 2 years of age.

Adverse drug reactions:

RCC: **♦Very common (≥10%):** anorexia, headache, bradycardia (asymptomatic), hypertension, abdominal pain, diarrhea, nausea, vomiting, alanine aminotransferase increased, aspartate aminotransferase increased, hair depigmentation, asthenia, fatigue, lab. abnormalities. **♦Common (1 to 10%):** neutropenia, thrombocytopenia, hypothyroidism, weight decreased, dysgeusia, transient ischemic attack, myocardial ischemia, QT prolongation, epistaxis, gastrointestinal haemorrhage, hematuria, venous thromboembolic events, dysphonia, dyspepsia, lipase elevations, hepatic function abnormal, hyperbilirubinemia, alopecia, palmar-plantar erythrodysesthesia syndrome, rash, skin depigmentation, proteinuria, chest pain. **♦Uncommon (0.1 to 1%):** ischemic stroke, cardiac dysfunction (such as a decrease in ejection fraction and congestive heart failure), myocardial infarction, torsade de pointes, cerebral hemorrhage, pulmonary hemorrhage, gastrointestinal perforation, gastrointestinal fistula. ***STS:*** **♦Very common (≥10%):** tumour pain, anorexia, weight decreased, dizziness, dysgeusia, headache, bradycardia (asymptomatic), hypertension, cough, dyspnea, abdominal pain, diarrhea, nausea, stomatitis, vomiting, alopecia, exfoliative rash, hair depigmentation, palmar-plantar erythrodysesthesia syndrome, skin depigmentation, musculoskeletal pain, myalgia, chest pain, fatigue, edema peripheral, lab. abnormalities. **♦Common (1 to 10%):** hypothyroidism, insomnia, cardiac dysfunction (such as a decrease in ejection fraction and congestive heart failure), QT prolongation, epistaxis, gastrointestinal haemorrhage, pulmonary hemorrhage, myocardial infarction, venous thromboembolic event, dysphonia, pneumothorax, dyspepsia, alanine aminotransferase increased, aspartate aminotransferase increased, dry skin, nail disorder, chills, vision blurred. **♦Uncommon (0.1 to 1%):** ischemic stroke, cerebral hemorrhage, hematuria, gastrointestinal fistula, hyperbilirubinemia, rash, proteinuria, asthenia.

The following adverse drug reactions have been identified during post-approval use of Votrient: ♦Very common (≥10%): Arthralgia. **♦Common (1 to 10%):** Infections (with or without neutropenia), muscle spasms, flatulence, gamma-glutamyl transpeptidase increased. **♦Uncommon (0.1 to 1%):** Thrombotic microangiopathy (TMA) (including thrombotic thrombocytopenic purpura and haemolytic uremic syndrome), pancreatitis, retinal detachment/tear, polycythemia. **♦Rare (0.01 to 0.1%)**: Posterior reversible encephalopathy syndrome (PRES), interstitial lung disease (ILD)/pneumonitis. **♦Not known**: Tumour lysis syndrome (TLS).

For a complete list of ADRS, consult full prescribing information.