NOVARTIS

JAKAVI®

(ruxolitinib)

5 mg, 10mg, 15 mg and 20 mg tablets

Basic Succinct Statement

Version 2.3

CODE: BSS RD 16 APR 18; APPR 25 SEP 19

This material is only meant for Healthcare Professionals

JAKAVI®

Important note: Before prescribing, consult full prescribing information.

Presentation: Tablets containing 5 mg, 10mg, 15 mg, and 20 mg ruxolitinib.

Indications: Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (MF), (also known as chronic idiopathic myelofibrosis), post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. Treatment of adult patients with polycythaemia vera (PV) who are resistant to or intolerant of hydroxyurea.

Dosage and administration: ♦Perform blood cell count before initiating Jakavi® therapy. Monitor complete blood counts every 2 to 4 weeks until optimal dose is reached. ♦Administration twice daily at the same time every day, with or without food. ♦Recommended starting dose for adults in MF: 15 mg (platelet count between 100,000 and 200,000/mm^3) and 20 mg (platelet count >200,000/ mm^3) twice daily ♦Recommended starting dose for adults in PV: 10mg twice daily. ♦Maximum starting dose of 5 mg twice daily in patients with a platelet count between 50,000/mm^3 and <100,000/ mm^3, caution in this patient population. ♦Interrupt treatment if platelet counts <50,000/ mm^3 or ANC <500/ mm^3. (MF and PV patients) or Hg < 8g/dL (in PV patients). ♦In PV, dose reduction to be considered if Hg < 12 g/dL and recommended if Hg < 10 g/dL. ♦Dose adjustment may be required due to thrombocytopenia or when used with strong CYP3A4 inhibitors or dual moderate inhibitors of CYP2C9 and CYP3A4 enzymes (e.g. fluconazole; avoid daily dose of fluconazole >200 mg). ♦4 weeks after initiating therapy dose may be increased at intervals of greater than 2 weeks to ensure adequate response. ♦Maximum dose is 25 mg twice daily ♦Treatment to be continued as long as the benefits outweigh the risks for the patient. ♦ Recommend to reduce the starting dose by approximately 50% in patients with renal impairment (Clcr <30 mL/min) or with hepatic impairment. The recommended starting dose for PV patients with severe renal impairment is 5mg twice daily. Monitor patients diagnosed with renal or hepatic impairment and reduce the dose as appropriate. ♦No dosage adjustment required for elderly patients.

Contraindications: Hypersensitivity to ruxolitinib or to any of the excipients. Pregnancy and lactation.

Warnings and precautions: ♦**Decrease in blood cell count:** hematologic adverse reactions, including thrombocytopenia, anemia and neutropenia have been reported with Jakavi treatment. Complete blood counts monitoring recommended. Dose reduction or interruption may be required in patients developing thrombocytopenia, anemia and neutropenia. ♦**Infections:** Serious bacterial, mycobacterial, fungal, viral and other opportunistic infections have occurred in patients treated with Jakavi. Patients should be assessed for the risk of developing serious infections. Physicians should carefully observe patients receiving Jakavi for signs and symptoms of infections and initiate appropriate treatment promptly. Jakavi therapy should not be started until active serious infections have resolved. Tuberculosis cases have been reported. Before starting treatment patients should be evaluated for active and inactive ("latent") tuberculosis, as per local recommendations. Progressive multifocal leukencephalopathy (PML) has been reported. Physicians should be alert for neuropsychiatric symptoms suggestive of PML. If PML suspected suspend treatment and until PML is excluded. Hepatitis B viral load (HBV-DNA titre) increases have been reported in patients with chronic HBV infections. Patients with chronic HBV infection should be treated and monitored according to clinical guidelines. ♦**Non-Melanoma Skin Cancer**

(NMSC): NMSC, including basal cell, squamous cell, and Merkel cell carcinoma, reported in Jakavi treated patients. Periodic skin examination recommended. ♦**Herpes Zoster:** Patients should be educated about early signs and symptoms of herpes zoster, and that be informed that treatment should be sought as early as possible. ♦**Lipid Abnormalities/Elevations:** Increases in lipid parameters, including total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides have been associated with Jakavi. Monitoring and treatment of dyslipidemia is recommended. ♦**Hepatic and severe renal impairment**: Due to increased Jakavi exposure, dose reduction is required.

Adverse drug reactions:

Very common (≥1/10): Urinary tract infections, anaemia, thrombocytopenia, neutropenia, bleeding (any bleeding including intracranial, and gastrointestinal bleeding, bruising and other bleeding), hypercholesterolaemia, hypertriglyceridaemia, dizziness, headache, alanine aminotransferase increased, aspartate aminotransferase increased, bruising, weight gain, hypertension.

Common (≥1/100 to <1/10): Pneumonia, herpes zoster, sepsis, flatulence, constipation

Uncommon (≥1/1,000 to <1/100): Tuberculosis.