For the use of a Registered Medical Practitioner only

Abridged Prescribing Information

Belumosudil Tablets 200mg
REZUROCK®

QUALITATIVE & QUANTITATIVE COMPOSITION:
Each film-coated tablet contains 200 mg Belumosudil (equivalent to 242.5 mg Belumosudil mesylate)

THERAPEUTIC INDICATION:
Rezurock® is indicated for the treatment of patients 12 years and older with chronic graft-versus-host disease (chronic GvHD) after failure of at least two prior lines of systemic therapy

DOSAGE AND ADMINISTRATION:
The recommended dose of Rezurock® is 200 mg given orally once daily at approximately the same time each day with a meal. If the patient misses a dose of Rezurock®, instruct the patient not to take extra doses to make up the missed dose

SAFETY RELATED INFORMATION:

SPECIAL POPULATIONS:
The safety and effectiveness of Belumosudil tablets in pediatric patients aged less than 12 years have not been established. No dose adjustment is recommended over the age of 65 years and patients with mild or moderate renal impairment. Use in patients with moderate hepatic impairment (Child-Pugh B) or severe hepatic impairment (Child-Pugh C) without liver GVHD is not recommended and no dose adjustment is recommended in patients with mild hepatic impairment (Child-Pugh A).

CONTRAINDICATIONS:
Hypersensitivity to this drug or to any of the excipients.

WARNINGS AND PRECAUTIONS:
Rezurock® can cause fetal harm when administered to a pregnant woman based on animal findings and mechanism of action. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Belumosudil and for at least one week after the last dose of Belumosudil.

INTERACTIONS:
Coadministration of Rezurock® with strong CYP3A inducers and proton pump inhibitors decreases Belumosudil exposure, which may reduce the efficacy of Belumosudil. Avoid coadministration of Belumosudil with UGT1A1 substrate, Pgp (e.g. dabigatran), OATP1B1, BCRP substrates and sensitive CYP1A2 substrates, for which minimal concentration changes may lead to serious toxicities. For detailed information, please refer to the interaction section in the prescribing information.

EFFECTS ON ABILITY TO DRIVE: Rezurock® has no influence on the ability to drive and use machines.

PREGNANCY AND LACTATION: Rezurock® is not recommended during pregnancy or breast-feeding.

UNDESIRABLE EFFECTS: The most common side effects of Rezurock® include tiredness or weakness, diarrhea, infections, nausea, shortness of breath, cough, swelling, high blood pressure, headache, muscle or bone pain and stomach (abdominal) pain.

For full prescribing information, refer to the company website www.sanofi.in

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