

PRODUCT ORDERING FORM

Distributed and marketed by	Sanofi - Phone: 800-981-2491 - Website: Sanofi.us
Product name	REZUROCK
Generic name	belumosudil
Product website	REZUROCKhcp.com
Indication ¹	REZUROCK is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.
Product information ¹	NDC: 79802-200-30 Description: REZUROCK 200 mg tablets (30-count bottle)
Wholesale acquisition price	\$19,043.38 per 30-count bottle

Ordering REZUROCK

Contact any of the authorized specialty distributors below to order REZUROCK for your account.

PHYSICIAN DISPENSING OFFICES

Cardinal Health™ Specialty Pharmaceutical Distribution

Phone: 1-877-453-3972

Fax: 1-877-274-9897

specialtyonline.cardinalhealth.com

Item number: 5699061

McKesson Specialty Health

Phone: 1-800-482-6700

Fax: 1-800-289-9285

mcs.mckesson.com

Item number: 5011227

Oncology Supply®

Phone: 1-800-633-7555

Fax: 1-800-248-8205

oncologysupply.com

Item number: 10260202

INSTITUTIONS/HOSPITALS

ASD Healthcare®

Phone: 1-800-746-6273

Fax: 1-800-547-9413

asdhealthcare.com

Item number: 10260202

Cardinal Health™ Specialty Pharmaceutical Distribution

Phone: 1-855-855-0708

Fax: 1-877-274-9897

orderexpress.cardinalhealth.com

Item number: 5699061

McKesson Plasma and Biologics

Phone: 1-877-625-2566

Fax: 1-888-752-7626

connect.mckesson.com

Item number: 2342103

Contact any of the authorized specialty pharmacies below to help get your patients started on REZUROCK.

Amber Specialty Pharmacy

Phone: 1-888-370-1724

Fax: 1-402-896-3774

amberpharmacy.com

Biologics by McKesson

Phone: 1-800-850-4306

Fax: 1-800-823-4506

biologics.mckesson.com

Onco360 Oncology Pharmacy

Phone: 1-877-662-6633

Fax: 1-877-662-6355

onco360.com

INDICATION

REZUROCK® (belumosudil) is indicated for the treatment of adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, REZUROCK can cause fetal harm when administered to a pregnant woman. 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 REZUROCK and for one week after the last dose

Please see additional Important Safety Information on the next page. Please see full [Prescribing Information](#).

Dispensing pack dimensions	Depth: 1.9 inches Height: 3.875 inches Width: 1.938 inches
How supplied¹	REZUROCK 200 mg tablets are supplied as pale yellow film-coated oblong tablets containing 200 mg of belumosudil (equivalent to 242.5 mg belumosudil mesylate). Each tablet is debossed with "KDM" on one side and "200" on the other side and is packaged as follows: 200 mg tablets in 30-count bottle; NDC 79802-200-30.
Storage and handling¹	Store at room temperature, 20 °C to 25 °C (68 °F to 77 °F); excursions permitted from 15 °C to 30 °C (59 °F to 86 °F). Dispense to patient in original container only. Store in original container to protect from moisture. Replace cap securely each time after opening. Do not discard desiccant.
Packaging¹	Sales unit: One 30-count bottle Units per case: 24
Product expiration	Expiration date printed on both 30-count bottle and carton.
Product returns	Phone: 888-379-6847 Email: customersupport@sanofi.com
Product information	Phone: 1-800-633-1610 Website: www.sanofimedicalinformation.com
Reimbursement and patient support	MyROCK ASSIST™ Phone: 1-844-523-6661 Fax: 1-833-635-1481 Website: MyROCKASSIST.com

IMPORTANT SAFETY INFORMATION (cont)

Adverse Reactions

- The most common ($\geq 20\%$) adverse reactions, including laboratory abnormalities, were infections, asthenia, nausea, diarrhea, dyspnea, cough, edema, hemorrhage, abdominal pain, musculoskeletal pain, headache, phosphate decreased, gamma glutamyl transferase increased, lymphocytes decreased, and hypertension
- Permanent discontinuation of REZUROCK due to adverse reactions occurred in 18% of patients. The adverse reactions which resulted in permanent discontinuation of REZUROCK in $> 3\%$ of patients included nausea (4%). Adverse reactions leading to dose interruption occurred in 29% of patients. The adverse reactions leading to dose interruption in $\geq 2\%$ were infections (11%), diarrhea (4%), and asthenia, dyspnea, hemorrhage, hypotension, liver function test abnormal, nausea, pyrexia, edema, and renal failure with (2% each)
- Monitor total bilirubin, aspartate aminotransferase (AST), and alanine aminotransferase (ALT) at least monthly

Drug Interactions

- **Proton Pump Inhibitors:** Belumosudil exhibits pH-dependent solubility. Concomitant use of REZUROCK with proton pump inhibitors decreases belumosudil exposure, which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK when used concomitantly with proton pump inhibitors
- **Strong CYP3A Inducers:** Belumosudil is a CYP3A substrate. Concomitant use of REZUROCK with strong CYP3A inducers decreases belumosudil exposure which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK when used concomitantly with strong CYP3A inducers
- **BCRP and OATP1B1 Substrates:** Avoid concomitant use with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions and decrease the BCRP substrates dosage(s) in accordance with the respective Prescribing Information.

Belumosudil is a BCRP inhibitor. Concomitant use of REZUROCK with BCRP substrates increases their plasma concentrations, which may increase the risk of adverse reactions related to these substrates.

Belumosudil is an OATP1B1 inhibitor. Concomitant use of REZUROCK with OATP1B1 substrates may increase their plasma concentrations. Monitor patients more frequently for adverse reactions of these substrates and decrease the OATP1B1 substrates dosage(s) in accordance with the respective Prescribing Information

Please see additional Important Safety Information on the next page. Please see full [Prescribing Information](#).

- **Certain CYP1A2 and CYP3A Substrates:** Avoid concomitant use of REZUROCK with drugs that are sensitive CYP1A2 or CYP3A substrates, for which minimal concentration changes may lead to serious toxicities. If concomitant use cannot be avoided, decrease the CYP1A2 or CYP3A substrate dosage(s) in accordance with the respective Prescribing Information. Belumosudil is a CYP1A2 and CYP3A inhibitor. Concomitant use of REZUROCK with sensitive CYP1A2 substrates (e.g., caffeine) or CYP3A substrates (e.g., midazolam) is predicted to increase CYP1A2 or CYP3A substrate exposure, which may increase the risk of adverse reactions related to these substrates
- **Certain UGT1A1 Substrates:** Avoid concomitant use of REZUROCK with drugs that are UGT1A1 substrates, for which minimal concentration changes may lead to serious toxicities. If concomitant use cannot be avoided, decrease the UGT1A1 substrates dosage(s) in accordance with the respective Prescribing Information. Belumosudil is a UGT1A1 inhibitor. Concomitant use of REZUROCK with a UGT1A1 substrate decreased plasma concentrations of the glucuronide metabolite of the UGT1A1 substrate. Concomitant use of belumosudil with other UGT1A1 substrates may increase their plasma concentrations, which may increase the risk of adverse reactions related to these substrates
- **Certain P-gp Substrates:** Avoid concomitant use of REZUROCK with drugs that are P-gp substrates, for which minimal concentration changes may lead to serious toxicities. If concomitant use cannot be avoided, decrease the P-gp substrates dosage(s) in accordance with the respective Prescribing Information. Belumosudil is a P-gp inhibitor. Concomitant use of REZUROCK with P-gp substrates increased their plasma concentrations, which may increase the risk of adverse reactions related to these substrates

Use in Specific Populations

- **Pregnancy:** There are no available human data on REZUROCK use in pregnant women to evaluate for a drug-associated risk. Advise pregnant women and females of reproductive potential of the potential risk to the fetus
- **Lactation:** There are no data available on the presence of belumosudil or its metabolites in human milk or the effects on the breastfed child, or milk production. Because of the potential for serious adverse reactions from belumosudil in the breastfed child, advise lactating women not to breastfeed during treatment with REZUROCK and for one week after the last dose
- **Pediatric Use:** The safety and effectiveness of REZUROCK in pediatric patients less than 12 years old have not been established
- **Geriatric Use:** Of the 186 patients with chronic GVHD in clinical studies of REZUROCK, 26% were 65 years and older. No clinically meaningful differences in safety or effectiveness of REZUROCK were observed in comparison to younger patients
- **Renal Impairment:** Treatment with REZUROCK has not been studied in patients with pre-existing severe renal impairment. For patients with pre-existing severe renal impairment, consider the risks and potential benefits before initiating treatment with REZUROCK
- **Hepatic Impairment:** Avoid use in patients with moderate hepatic impairment (Child- Pugh B) or severe hepatic impairment (Child-Pugh C) without liver GVHD. No dose adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A)

Please see additional Important Safety Information on the previous page. Please see full [Prescribing Information](#).

Reference: 1. REZUROCK. Package insert. Kadmon Pharmaceuticals, LLC.