REZUROCK[®] (belumosudil) tablets

PRODUCT ORDERING FORM

Distributed and marketed by

Product name

Generic name

Product website

Indication¹

Product information¹

Wholesale acquisition price

Ordering REZUROCK

Kadmon, a Sanofi Company - Phone: 800-981-2491 - Website: Sanofi.us

REZUROCK			
belumosudil			
REZUROCKhcp.com			
REZUROCK is indicated for the treatment of ad graft-versus-host disease (chronic GVHD) afte			
NDC: 79802-200-30 Description: REZUROCK 200 mg tablets (30-co	unt bottle)		
\$17,874.83 per 30-count bottle			
Contact any of the authorized specialty dist	ributors below to order	REZUROCK for	your account.
PHYSICIAN DISPENSING OFFICES		INSTITUTIONS	/HOSPITALS
Cardinal Health™ Specialty Pharmaceutical Distribution Phone: 1-877-453-3972 Fax: 1-877-274-9897 specialtyonline.cardinalhealth.com		ASD Healthcar Phone: 1-800-7 Fax: 1-800-547 asdhealthcar Item number:	746-6273 7-9413 <mark>e.com</mark>
Item number: 5699061		Cardinal Healt	th™ Specialty
McKesson Specialty Health Phone: 1-800-482-6700 Fax: 1-800-289-9285 mscs.mckesson.com		Phone: 1-855-8 Fax: 1-877-274 orderexpress	-9897 .cardinalhealth.com
Item number: 5011227		Item number: 5699061	
Oncology Supply® Phone: 1-800-633-7555 Fax: 1-800-248-8205 oncologysupply.com Item number: 10260202	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 phan on REZUROCK.	rmacies below to help (get your patier	its started
Amber Specialty Pharmacy Phone: 1-888-370-1724 Fax: 1-402-896-3774 amberpharmacy.com	Biologics by McKesson Phone: 1-800-850-430 Fax: 1-800-823-4506 biologics.mckesson.c	6	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

Adverse Reactions

The most common (> 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

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 supplied ¹	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 handling ¹	Store at room temperature, 20°C to 25°C (68°F to 77°F); excursions permitted from 15°C and 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.		
Packaging ¹	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	Kadmon ASSIST™ Phone: 1-844-KADMON1 (523-6661) Fax: 1-833-635-1481 Website: KadmonASSIST.com		

IMPORTANT SAFETY INFORMATION (cont)

Adverse Reactions (cont)

- 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 ≥ 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

- Strong CYP3A Inducers: Coadministration of REZUROCK with strong CYP3A inducers decreases belumosudil exposure, which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK to 200 mg twice daily when coadministered with strong CYP3A inducers
- Proton Pump Inhibitors: Coadministration of REZUROCK with proton pump inhibitors decreases belumosudil exposure, which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK to 200 mg twice daily when coadministered with proton pump inhibitors
- Certain UGT1A1 substrates: Avoid coadministration of REZUROCK with UGT1A1 substrates, for which minimal concentration changes may lead to serious toxicities. If coadministration cannot be avoided, decrease the UGT1A1 substrates dosage(s) in accordance with the respective Prescribing Information. REZUROCK is an inhibitor of UGT1A1. Coadministration of REZUROCK with a UGT1A1 substrate decreased plasma concentrations of the glucuronide metabolite, which may increase the risk of adverse reactions related to sensitive substrates of UGT1A1.
- Certain P-gp, OATP1B1, and BCRP substrates: Avoid coadministration of REZUROCK with P-gp, OATP1B1, and BCRP substrates, for which minimal concentration changes may lead to serious toxicities. If coadministration cannot be avoided, decrease the P-gp, OATP1B1, and BCRP substrates dosage(s) in accordance with the respective Prescribing Information. REZUROCK is an inhibitor of P-gp, OATP1B1, and BCRP. Coadministration of REZUROCK with P-gp, OATP1B1, and BCRP 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; 2024.

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