INDICATIONS AND USAGE
REZUROCK is a kinase inhibitor 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. (1)

DOSE AND ADMINISTRATION
Recommended Dosage: 200 mg taken orally once daily with food. (2.1)

Dosage Forms and Strengths
Tablet: 200 mg. (3)

CONTRAINDICATIONS
None. (4)

WARNINGS AND PRECAUTIONS
Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. (5.1, 8.1, 8.3)

ADVERSE REACTIONS
To report SUSPECTED ADVERSE REACTIONS, contact Kadmon Pharmaceuticals, LLC at 1-800-533-1610 or FDA at 1-888-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS
Strong CYP3A Inducers: Increase REZUROCK dosage to 200 mg twice daily. (7.1)

Proton Pump Inhibitors: Increase REZUROCK dosage to 200 mg twice daily. (7.1)

USE IN SPECIFIC POPULATIONS
Pediatric Use

8.3 Females and Males of Reproductive Potential

8.4 Pediatric Use

8.5 Geriatric Use

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

14.1 Chronic Graft versus Host Disease

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed

Revised: 04/2023

Table 1: Recommended Dosage Modifications for REZUROCK for Adverse Reactions (continued)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Severity</th>
<th>REZUROCK Dosage Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3 AST or ALT (5x to 20x ULN) or Grade 2 bilirubin (1.5x to 3x ULN)</td>
<td>Hold REZUROCK until recovery of bilirubin, AST and ALT to Grade 0–1, then resume REZUROCK at the recommended dose.</td>
<td></td>
</tr>
<tr>
<td>Grade 4 AST or ALT (more than 20x ULN) or Grade 3 bilirubin (more than 3x ULN)</td>
<td>Discontinue REZUROCK permanently.</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Recommended Dosage Modifications for REZUROCK for Adverse Reactions

<table>
<thead>
<tr>
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<th>Severity</th>
<th>REZUROCK Dosage Modifications</th>
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<tbody>
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<td>Hold REZUROCK until recovery of bilirubin, AST and ALT to Grade 0–1, then resume REZUROCK at the recommended dose.</td>
<td></td>
</tr>
<tr>
<td>Grade 4 AST or ALT (more than 20x ULN) or Grade 3 bilirubin (more than 3x ULN)</td>
<td>Discontinue REZUROCK permanently.</td>
<td></td>
</tr>
</tbody>
</table>

Based on CTCAE v 4.03

2.3 Dosage Modification Due to Drug Interactions

Strong CYP3A Inducers

Increase the dosage of REZUROCK to 200 mg twice daily when coadministered with strong CYP3A inducers [see Drug Interactions (7.1)].

Proton Pump Inhibitors

Increase the dosage of REZUROCK to 200 mg twice daily when coadministered with proton pump inhibitors [see Drug Interactions (7.1)].

3 DOSAGE FORMS AND STRENGTHS

Each 200 mg tablet is a pale yellow film-coated oblong tablet debossed with “KDM” on one side and “200” on the other side.

None. (4)

5 WARNINGS AND PRECAUTIONS

5.1 Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, REZUROCK can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of belumosudil to pregnant rats and rabbits during the period organogenesis caused adverse developmental outcomes including embryo-fetal mortality and malformations at maternal exposures (AUC) less than those in patients at the recommended dose. 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 at least one week after the last dose [see Use in Specific Populations (8.1, 8.3), Nonclinical Toxicology (13.1)].
6 ADVERSE REACTIONS

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely variable conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared with rates of clinical trials of another drug and may not reflect the rates observed in practice.

Chronic Graft versus Host Disease

In two clinical trials (Study KD025-213 and Study KD025-208), 83 adult patients with chronic GVHD were treated with REZUROCK 200 mg once daily [see Clinical Studies (14.1)]. The median duration of treatment was 9.2 months (range 0.5 to 44.7 months). Fatal adverse reaction was reported in one patient with severe nausea, vomiting, diarrhea and multi-organ failure.

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 asthma, dyspnea, hemorrhage, hypotension, liver function test abnormal, nausea, pyrexia, edema, and renal failure with (2% each).

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. Table 2 summarizes the nonlaboratory adverse reactions.

Table 2: Nonlaboratory Adverse Reactions in ≥10% Patients with Chronic GVHD Treated with REZUROCK

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>All Grades (%)</th>
<th>Grades 3–4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection (pathogen not specified)</td>
<td>53</td>
<td>16</td>
</tr>
<tr>
<td>Viral infection</td>
<td>19</td>
<td>4</td>
</tr>
<tr>
<td>Bacterial infection</td>
<td>16</td>
<td>4</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthenia</td>
<td>46</td>
<td>4</td>
</tr>
<tr>
<td>Edema</td>
<td>27</td>
<td>1</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>42</td>
<td>4</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>35</td>
<td>5</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>22</td>
<td>1</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>33</td>
<td>5</td>
</tr>
<tr>
<td>Cough</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>Nasal congestion</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Vascular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>23</td>
<td>5</td>
</tr>
<tr>
<td>Hypertension</td>
<td>21</td>
<td>7</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
<td>22</td>
<td>4</td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>Nervous system</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>Metabolism and nutrition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>17</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 3 summarizes the laboratory abnormalities in REZUROCK.

Table 3: Selected Laboratory Abnormalities in Patients with Chronic GVHD Treated with REZUROCK

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Grade 0–1 Baseline (%)</th>
<th>Grade 2–4 Max Post (%)</th>
<th>Grade 3–4 Max Post (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phosphate decreased</td>
<td>76 (28)</td>
<td>28 (7)</td>
<td>28 (7)</td>
</tr>
<tr>
<td>Gamma Glutamyl Transferase</td>
<td>47 (21)</td>
<td>21 (11)</td>
<td>21 (11)</td>
</tr>
<tr>
<td>Calcium increased</td>
<td>82 (12)</td>
<td>12 (1)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Alkaline Phosphatase increased</td>
<td>80 (9)</td>
<td>9 (0)</td>
<td>9 (0)</td>
</tr>
<tr>
<td>Potassium increased</td>
<td>82 (7)</td>
<td>7 (1)</td>
<td>7 (1)</td>
</tr>
<tr>
<td>Alanine Aminotransferase</td>
<td>83 (7)</td>
<td>7 (2)</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Creatinine increased</td>
<td>83 (4)</td>
<td>4 (0)</td>
<td>4 (0)</td>
</tr>
<tr>
<td>Hematology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lymphocytes decreased</td>
<td>62 (29)</td>
<td>29 (13)</td>
<td>29 (13)</td>
</tr>
<tr>
<td>Hemoglobin decreased</td>
<td>79 (11)</td>
<td>11 (1)</td>
<td>11 (1)</td>
</tr>
<tr>
<td>Platelets decreased</td>
<td>82 (10)</td>
<td>10 (5)</td>
<td>10 (5)</td>
</tr>
<tr>
<td>Neutrophil Count decreased</td>
<td>83 (8)</td>
<td>8 (4)</td>
<td>8 (4)</td>
</tr>
</tbody>
</table>

7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on REZUROCK

Strong CYP3A Inducers

Coadministration of REZUROCK with strong CYP3A inducers decreases belumosudil exposure [see Clinical Pharmacology (12.3)], which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK when coadministered with strong CYP3A inducers [see Dosage and Administration (2.3)].

Proton Pump Inhibitors

Coadministration of REZUROCK with proton pump inhibitors decreases belumosudil exposure [see Clinical Pharmacology (12.3)], which may reduce the efficacy of REZUROCK. Increase the dosage of REZUROCK when coadministered with proton pump inhibitors [see Dosage and Administration (2.3)].
8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on findings from animal studies and the mechanism of action [see Clinical Pharmacology (12.1)], REZUROCK can cause fetal harm when administered to pregnant women. There are no available human data on REZUROCK use in pregnant women to evaluate for a drug-associated risk. In animal reproduction studies, administration of belumosudil to pregnant rats and rabbits during the period of organogenesis resulted in adverse developmental outcomes, including alterations to growth, embryo-fetal mortality, and embryo-fetal malformations at maternal exposures (AUC) approximately ≥3- (rat) and ≥0.07 (rabbit) times the human exposure (AUC) at the recommended dose (see Animal data). Advise pregnant women and females of reproductive potential of the potential risk to the fetus.

In the U.S., general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal data

Embryo-fetal development studies were conducted in rats with administration of belumosudil to pregnant animals during the period of organogenesis at oral doses of 25, 50, 150, and 300 mg/kg/day in a pilot study and doses of 15, 50, and 150 mg/kg/day in a pivotal study. In the pilot study, maternal toxicity and embryo-fetal developmental effects were observed. Maternal toxicity (reduced body weight gain) occurred at 150 and 300 mg/kg/day doses. Increased post-implantation loss occurred at 50 and 300 mg/kg/day. In an embryo-fetal development study in rabbits, pregnant animals administered oral doses of belumosudil at 50, 125, and 225 mg/kg/day during the period of organogenesis resulted in maternal toxicity and embryo-fetal developmental effects. Maternal toxicity (body weight loss and mortality) was observed at doses ≥125 mg/kg/day. Embryo-fetal effects were observed at doses ≥50 mg/kg/day and included spontaneous abortion, increased post-implantation loss, decreased percentage of live fetuses, malformations, and decreased fetal body weight. Malformations included those in the tail (short), ribs (branched, fused or deformed), sternum (fused), and neural arches (fused, misaligned, and deformed). The exposure (AUC) at 50 mg/kg/day in rabbits is approximately 3 times the human exposure at the recommended dose of 200 mg.

In an embryo-fetal developmental study in rabbits, pregnant animals administered oral doses of belumosudil at 50, 125, and 225 mg/kg/day during the period of organogenesis resulted in maternal toxicity and embryo-fetal developmental effects. Malformed rats were observed in comparison to younger patients. There are no data available on human safety of belumosudil in pregnant women to evaluate for a drug-associated risk. In animal reproduction studies, administration of belumosudil to pregnant animals during the period of organogenesis resulted in adverse developmental outcomes, including alterations to growth, embryo-fetal mortality, and embryo-fetal malformations at maternal exposures (AUC) approximately ≥3- (rat) and ≥0.07 (rabbit) times the human exposure (AUC) at the recommended dose (see Animal data). Advise pregnant women and females of reproductive potential of the potential risk to the fetus.

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8.2 Lactation

Risk Summary

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 at least one week after the last dose.

8.3 Females and Males of Reproductive Potential

REZUROCK can cause fetal harm when administered to a pregnant woman [see Use in Specific Populations (8.1)].

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating treatment with REZUROCK.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with REZUROCK and for at least one week after the last dose of REZUROCK. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Males

Advise males with female partners of reproductive potential to use effective contraception during treatment with REZUROCK and for at least one week after the last dose of REZUROCK.

Infertility

Females

Based on findings from rats, REZUROCK may impair female fertility. The effect on fertility is reversible [see Nonclinical Toxicology (13.1)].

Males

Based on findings from rats and dogs, REZUROCK may impair male fertility. The effects on fertility are reversible [see Nonclinical Toxicology (13.1)].

8.4 Pediatric Use

The safety and effectiveness of REZUROCK have been established in pediatric patients 12 years and older. Use of REZUROCK in this age group is supported by evidence from adequate and well-controlled studies of REZUROCK in adults with additional population pharmacokinetic data demonstrating that age and body weight had no clinically meaningful effect on the pharmacokinetics of drug substance, that the exposure of drug substance is expected to be similar between adults and pediatric patients age 12 years and older, and that the course of disease is sufficiently similar in adult and pediatric patients to allow extrapolation of data in adults to pediatric patients.

The safety and effectiveness of REZUROCK in pediatric patients less than 12 years old have not been established.

8.5 Geriatric Use

Of the 184 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.

11 DESCRIPTION

Belumosudil is a kinase inhibitor. The active pharmaceutical ingredient in belumosudil mesylate with the molecular formula C$_{23}$H$_{24}$N$_{2}$O$_{5}$S and the molecular weight is 545.62 g/mol. The chemical name for belumosudil mesylate is 2-[(3-(1H-indazolo[5-3-1-5]pyridon-3-yl)-2-quinazolyl)[phenoxo]-N-(propan-2-yl)] acetamide methanesulfonate (1:1). The chemical structure is as follows:...
13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenicity studies have not been conducted with belumosudil.

Mutagenesis

Belumosudil was not genotoxic in an in vitro bacterial mutagenicity (Ames) assay, in vitro chromosome aberration assay in human peripheral blood lymphocytes (HPBL) or an in vivo rat bone marrow micronucleus assay.

Impairment of Fertility

In a combined male and female rat fertility study, belumosudil-treated male animals were mated with untreated females, or untreated males were mated with belumosudil-treated females. Belumosudil was administered orally at doses of 50, 150 or 275 mg/kg/day to male rats 70 days prior to and throughout the mating period, and to female rats 14 days prior to mating and up to Gestation Day 7. At the dose of 275 mg/kg/day, adverse findings in female rats (treated with belumosudil or untreated but mated with treated males) included increased pre- or post-implantation loss and decreased number of viable embryos. Administration of belumosudil to male rats at a dose of 275 mg/kg/day resulted in abnormal sperm findings (reduced motility, reduced count, and increased percentage of abnormal sperm), and testes/epididymis organ changes (reduced weight and degeneration). Fertility was reduced in both treated males or females at the 275 mg/kg/day dose and reached statistical significance in males. Adverse changes in male and female reproductive organs also occurred in general toxicology studies; findings included spermatozoa degeneration at abelumosudil dose of 35 mg/kg/day in dogs and decreased follicular development in ovaries at 275 mg/kg/day in rats. Changes were partially or fully reversed during the recovery period. The exposure (AUC) at the doses of 35 mg/kg/day in dogs, and 275 mg/kg/day in rats is 0.5 times and 8–9 times, respectively, the clinical exposure at the recommended dose of 200 mg daily.

14 CLINICAL STUDIES

14.1 Chronic Graft versus Host Disease

Study KD025-213 (NCT03640481) was a randomized, open-label, multicenter study of REZUROCK for treatment of patients with chronic GVHD who had received 2 to 5 prior lines of systemic therapy and required additional treatment. Patients were excluded from the studies if platelets were <50 x 10^9/L; absolute neutrophil count <1.5 x 10^9/L; AST or ALT >3 x ULN; total bilirubin >1.5 x ULN; QTcF >480 ms; eGFR <30 mL/min/1.73 m^2; or FEV1 <39%. There were 66 patients treated with REZUROCK 200 mg taken orally once daily. Concomitant treatment with supportive care therapies for chronic GVHD was permitted. Concomitant treatment with GVHD prophylaxis and standard care systemic chronic GVHD therapies was permitted as long as the subject has been on a stable dose as follows: for at least 2 weeks prior to study. Initiation of new systemic chronic GVHD therapy while on study was not permitted.

Demographics and baseline characteristics are summarized in Table 4.

Table 4: Demographics and Baseline Characteristics of Patients with Chronic GVHD

<table>
<thead>
<tr>
<th>Age, Median, Years (minimum, maximum) (N=65)</th>
<th>200 mg once daily</th>
<th>200 mg once daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥65 Years, n (%)</td>
<td>17 (26)</td>
<td>23 (35)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>42 (65)</td>
<td>31 (48)</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>54 (83)</td>
<td>3 (2, 6)</td>
</tr>
<tr>
<td>White</td>
<td>6 (9)</td>
<td>3 (2, 6)</td>
</tr>
<tr>
<td>Black</td>
<td>5 (8)</td>
<td>15 (23)</td>
</tr>
<tr>
<td>Other or Not Reported</td>
<td>3 (2, 6)</td>
<td>15 (23)</td>
</tr>
<tr>
<td>Median (range) time (months) from Chronic GVHD Diagnosis</td>
<td>25.3 (1, 162.4)</td>
<td>23 (35)</td>
</tr>
<tr>
<td>≥4 Organs Involved, n (%)</td>
<td>31 (48)</td>
<td>31 (48)</td>
</tr>
<tr>
<td>Median (range) Number of Prior Lines of Therapy</td>
<td>3 (2, 6)</td>
<td>3 (2, 6)</td>
</tr>
<tr>
<td>Number of Prior Lines of Therapy, n (%)</td>
<td>23 (35)</td>
<td>23 (35)</td>
</tr>
<tr>
<td>2</td>
<td>12 (19)</td>
<td>12 (19)</td>
</tr>
<tr>
<td>3</td>
<td>15 (23)</td>
<td>15 (23)</td>
</tr>
<tr>
<td>≥5</td>
<td>21 (32)</td>
<td>21 (32)</td>
</tr>
<tr>
<td>Prior chronic GVHD treatment with ibrutinib, n (%)</td>
<td>20 (31)</td>
<td>20 (31)</td>
</tr>
<tr>
<td>Refractory to Last Therapy, n (%)</td>
<td>43/55 (78)</td>
<td>43/55 (78)</td>
</tr>
<tr>
<td>Severe chronic GVHD, n (%)</td>
<td>46 (71)</td>
<td>46 (71)</td>
</tr>
<tr>
<td>Median (range) Global Severity Rating</td>
<td>7 (2, 9)</td>
<td>7 (2, 9)</td>
</tr>
</tbody>
</table>

REZUROCK 200 mg once daily

Table 5: Overall Response Rate through Cycle 7 Day 1 for Patients with Chronic GVHD in Study KD025-213

<table>
<thead>
<tr>
<th>Overall Response Rate (ORR)</th>
<th>REZUROCK 200 mg once daily (N=65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Response</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>Partial Response</td>
<td>45 (69%)</td>
</tr>
</tbody>
</table>

The efficacy of REZUROCK was based on overall response rate (ORR) through Cycle 7 Day 1 where overall response included complete response or partial response according to the 2014 NIH Response Criteria. The ORR results are presented in Table 5. The ORR was 75% (95% CI: 63, 83). The median duration of response, calculated from first response to progression, death, or new systemic therapies for chronic GVHD, was 1.9 months (95% CI: 1.2, 2.9). The median time to first response was 1.8 months (95% CI: 1.0, 1.9). In patients who achieved response, no death or new systemic therapy initiation occurred in 82% (95% CI: 46, 74) of patients for at least 12 months since response.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Embryo-fetal Toxicity:

- Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to inform their healthcare provider of a known or suspected pregnancy [see Warnings and Precautions (5.1), Use in Specific Populations (8.1, 8.3)].
- Advise females of reproductive potential to use effective contraceptive during treatment with REZUROCK and for at least one week after the last dose [see Warnings and Precautions (5.1)].
- Advise males with female partners of reproductive potential to use effective contraceptive during treatment with REZUROCK and for at least one week after the last dose [see Use in Specific Populations (8.3)].

Lactation:

- Advise women not to breastfeed during treatment with REZUROCK and for at least one week after the last dose [see Use in Specific Populations (8.3)].

Infertility:

- Advise males and females of reproductive potential that REZUROCK may impair fertility [see Use in Specific Populations (8.3)].

Administration:

- Advise patients to take REZUROCK orally once daily with food according to their physician’s instructions and that the oral dosage (tablets) should be swallowed whole with a glass of water, without cutting, crushing or chewing the tablets approximately the same time each day [see Dosage and Administration (2.1)].
- Advise patients that in the event of a missed daily dose of REZUROCK, it should be taken as soon as possible on the same day with a return to the normal schedule the following day. Patients should not take extra doses to make up the missed dose [see Dosage and Administration (2.1)].

Drug Interactions:

- Advise patients to inform their health care providers of all concomitant medications, including prescription medications, over-the-counter drugs, vitamins, and herbal products [see Drug Interactions (7)].

Distributed and marketed by:
Kadmon Pharmaceuticals, LLC
Bridgewater, NJ 08807
A SANDOFI COMPANY
1-800-633-1610
PATIENT INFORMATION

REZUROCK (REZ-ur-ok) (belumosudil) tablets

What is REZUROCK?
REZUROCK is a prescription medicine used to treat adults and children 12 years of age and older with chronic graft-versus-host disease (chronic GVHD) after you have received at least 2 prior treatments (systemic therapy) and they did not work. It is not known if REZUROCK is safe and effective in children less than 12 years old.

Before taking REZUROCK, tell your healthcare provider about all of your medical conditions, including if you:
- have kidney or liver problems.
- are pregnant or plan to become pregnant. REZUROCK can harm your unborn baby. If you are able to become pregnant, your healthcare provider will do a pregnancy test before starting treatment with REZUROCK. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with REZUROCK.
  - Females who can become pregnant should use effective birth control during treatment with REZUROCK and for at least 1 week after the last dose.
  - Males with female partners who can become pregnant should use effective birth control during treatment with REZUROCK and for at least 1 week after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if REZUROCK passes into breast milk. Do not breastfeed during treatment with REZUROCK and for at least 1 week after the last dose.
- have kidney or liver problems.
- are taking any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. REZUROCK may affect the way other medicines work, and other medicines may affect the way REZUROCK works.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. REZUROCK may affect the way other medicines work, and other medicines may affect the way REZUROCK works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take REZUROCK?
- Take REZUROCK exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking REZUROCK without first talking to your healthcare provider.
- Take REZUROCK 1 time a day with a meal.
- Take REZUROCK at about the same time each day.
- Swallow REZUROCK tablets whole with a glass of water.
- Do not cut, crush, or chew REZUROCK tablets.
- Your healthcare provider will do blood tests to check your liver at least 1 time a month during treatment with REZUROCK.
- If you miss a dose of REZUROCK, take it as soon as you remember on the same day. Take your next dose of REZUROCK at your regular time on the next day. Do not take extra doses of REZUROCK to make up for a missed dose.
- If you take too much REZUROCK, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of REZUROCK?
The most common side effects of REZUROCK include:
- infections
- tiredness or weakness
- nausea
- diarrhea
- shortness of breath
- cough

Your healthcare provider may change your dose of REZUROCK, temporarily stop, or permanently stop treatment with REZUROCK if you have certain side effects. REZUROCK may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you. These are not all the possible side effects of REZUROCK. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Kadmon Pharmaceuticals, LLC at 1-800-633-1610.

How should I store REZUROCK?
- Store REZUROCK at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep REZUROCK in its original container. The REZUROCK bottle contains a desiccant packet to help keep your tablets dry (protect from moisture). Keep the desiccant in the bottle.
- Tightly close the REZUROCK bottle after you take your dose.

Keep REZUROCK and all medicines out of the reach of children.

General information about the safe and effective use of REZUROCK.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use REZUROCK for a condition for which it was not prescribed. Do not give REZUROCK to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about REZUROCK that is written for health professionals.

What are the ingredients in REZUROCK?
Active ingredient:belumosudil mesylate
Inactive ingredients:
- Tablet core: microcrystalline cellulose, hypromellose, croscarmellose sodium, colloidal silicon dioxide, and magnesium stearate.
- Tablet coating: polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide and yellow iron oxide.

Distributed and marketed by Kadmon Pharmaceuticals, LLC, Bridgewater, NJ 08807, A SANOFI COMPANY

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For more information, call 1-800-633-1610 or go to www.REZUROCK.com.

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