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Prescribing information can be found on this link.

REZUROCK® ▼
(belumosudil) tablets

SAFETY PROFILE

Explore when considering REZUROCK in the treatment of cGVHD for patients aged 12 years and older who have received at least two prior lines of systemic therapy.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com.

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REZUROCK was **generally well tolerated** in patients with cGVHD[1]

Safety was evaluated across 2 clinical studies (n=186)[2,3]

The most common adverse reactions leading to discontinuation were nausea (2.4%) and headache (2.4%). Adverse reactions leading to dose interruption occurred in 9.6% of patients and were mainly investigations (3.6%), including ALT increased, GGT increased and blood creatine phosphokinase increased (1.2% each), and infections (2.4%)[1]

From Rezurock Summary of Product Characteristics, dated July 2024.[1]

The most common adverse reactions (≥5%) were asthenia (21.0%), nausea (12.4%), liver function test abnormalities of elevation of AST (7.5%), elevation of ALT (7.0%) and elevation of GGT (4.8%), headache (8.6%), diarrhoea (7.0%) and musculoskeletal pain (5.9%)[1]

From Rezurock Summary of Product Characteristics, dated July 2024.[1]

Serious adverse reactions were pneumonia (1.1%), cellulitis, infectious colitis, staphylococcal bacteraemia, diarrhoea, nausea, vomiting, microangiopathic haemolytic anaemia, multiple organ dysfunction syndrome and cGVHD (0.5% each)[1]

From Rezurock Summary of Product Characteristics, dated July 2024.[1]

There were **no reports of CMV infection** in both the ROCKstar and the foundational, dose-finding KD025-208 studies, and only **1 report of CMV reactivation** in total[2,3]

ROCKstar data up to 19 August 2020 included.[1]

In the ROCKstar and KD025-208 clinical studies of REZUROCK, **grade ≥3 cytopenias** were reported in **<4%** and **4%** of patients, respectively[2,3]

ROCKstar data up to 19 August 2020 included.[1]

In the 3-year follow-up to the 2021 ROCKstar study, no new safety signals were observed.[4]

Please refer to the full Summary of Product Characteristics before prescribing.

cGVHD, chronic graft-versus-host disease; CMV, cytomegalovirus.

References: 1. REZUROCK. Summary of Product Characteristics. **2.** Jagasia M, Lazaryan A, Bachier CR, *et al*. ROCK2 inhibition with belumosudil (KD025) for the treatment of chronic graft-versus-host disease. *J Clin Oncol*. 2021;39 (17):1888-1898. doi:10.1200/JCO.20.02754. **3.** Cutler C, Lee SJ, Arai S, *et al*; on behalf of the ROCKstar Study Investigators. Belumosudil for chronic graft-versus-host disease after 2 or more prior lines of therapy: the ROCKstar Study. *Blood*.2021;138 (22):2278-2289. doi:10.1182/blood.2021012021. **4.** Lee SJ, Cutler C, Pavletic S, *et al*. Belumosudil for chronic graft-versus-host disease after 2 or more lines of systemic therapy: 3-year follow-up to the ROCKstar study. Poster presented at: Tandem Meetings; February 21, 2024; San Antonio, TX.

Safety results across 2 clinical studies pooled for analysis[1]

Adverse reactions (≥2%) in patients with chronic GVHD who received belumosudil[1]

Table adapted from Rezurock Summary of Product Characteristics, dated July 2024.[1]

Pooled chronic GVHD (N=186)	All severity grades Frequency category	All grades[a] (%)	Grade 3-4[a] (%)
Infections and infestations			
Upper respiratory tract infections[b]	**Common**	7 (3.8%)	0
Lower respiratory tract infections[c]	**Common**	5 (2.7%)	2 (1.1%)
Blood and lymphatic system disorders			
Anaemia*	**Common**	6 (3.2%)	1 (0.5%)
Leukopenia[d]*	**Common**	9 (4.8%)	3 (1.6%)
Platelet count decreased	**Common**	5 (2.7%)	0
Metabolism and nutrition disorders			
Decreased appetite	**Common**	7 (3.8%)	1 (0.5%)
Hyperglycaemia	**Common**	7 (3.8%)	0
Nervous system disorders			
Headache	**Common**	16 (8.6%)	1 (0.5%)
Neuropathy peripheral	**Common**	6 (3.2%)	0
Dizziness	**Common**	4 (2.2%)	0
Vascular disorders			
Hypertension	**Common**	6 (3.2%)	3 (1.6%)
Respiratory, thoracic and mediastinal disorders			
Dyspnea[e]	**Common**	7 (3.8%)	0
Cough[f]	**Common**	7 (3.8%)	0
Gastrointestinal disorders			
Nausea	**Very Common**	23 (12.4%)	2 (1.1%)
Diarrhoea	**Common**	13 (7.0%)	2 (1.1%)
Vomiting	**Common**	9 (4.8%)	1 (0.5%)
Abdominal pain[g]	**Common**	5 (2.7%)	0
Constipation	**Common**	5 (2.7%)	1 (0.5%)
Hepatobiliary disorders			
Aspartate aminotransferase increased	**Common**	14 (7.5%)	3 (1.6%)
Alanine aminotransferase increased	**Common**	13 (7.0%)	2 (1.1%)
Gamma-glutamyltransferase increased	**Common**	9 (4.8%)	2 (1.1%)
Skin and subcutaneous tissue disorders			
Pruritus	**Common**	5 (2.7%)	0
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain[h]	**Common**	11 (5.9%)	0
Muscle spasms	**Common**	8 (4.3%)	0
Blood alkaline phosphatase increased	**Common**	7 (3.8%)	0
Blood creatine phosphokinase increased	**Common**	4 (2.2%)	1 (0.5%)
Renal and urinary disorders			
Blood creatinine increased	**Common**	4 (2.2%)	0
General disorders and administration site conditions			
Asthenia[i]	**Very Common**	39 (21.0%)	5 (2.7%)
Oedema[j]	**Common**	9 (4.8%)	0
Pyrexia	**Common**	3 (1.6%)	0
Investigations			
Weight decreased	**Common**	6 (3.2%)	0

Please refer to the full Summary of Product Characteristics before prescribing.

[a]National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 5.0 and version 4.03 for studies KD025-208 and KD025-213, respectively.

[b]includes upper respiratory tract infection, sinusitis.

[c]includes pneumonia, bronchitis, bronchitis viral.

[d]includes leukopenia, neutropenia, neutrophil count decreased, white blood cell count decreased, lymphocyte count decreased.

[e]includes dyspnea, dyspnea exertional.

[f]includes cough, productive cough.

[g]includes abdominal pain, abdominal pain upper.

[h]includes arthralgia, pain in extremity, back pain, neck pain.

[i]includes fatigue, asthenia, malaise.

[j]includes oedema peripheral, face oedema, localized oedema, swelling.

*See description of selected adverse reactions in full SmPC.

GVHD, graft-versus-host disease.

Reference: 1. REZUROCK. Summary of Product Characteristics.