RYTELO™
(imetelstat) for Injection 47 mg 188 mg

PRODUCT ORDERING

INDICATION

RYTELO (imetelstat) is indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombocytopenia

RYTELO can cause thrombocytopenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased platelets occurred in 65% of patients with MDS treated with RYTELO.

Monitor patients with thrombocytopenia for bleeding. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer platelet transfusions as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide.

Accessing RYTELO Through Geron's Authorized Specialty Distributors and Specialty Pharmacies

You can take an active role in ensuring the security of the pharmaceutical supply chain by sourcing products only from authorized distributors or pharmacies.

RYTELO can be purchased from the specialty distributors listed below.

Specialty Distributors

Authorized Distributor	Phone	Fax	Website
ASD Healthcare	1-800-746-6273	1-800-547-9413	asdhealthcare.com
Cardinal Health Puerto Rico	1-787-625-4200	1-787-625-4398	orderexpress.cardinalhealth.com
Cardinal Health Specialty Pharmaceutical Distribution	1-855-855-0708	1-614-553-6301	orderexpress.cardinalhealth.com
McKesson Plasma & Biologics	1-877-625-2566	1-888-752-7626	connect.mckesson.com
McKesson Specialty Health	1-800-482-6700	1-855-824-9489	mscs.mckesson.com
Oncology Supply	1-800-633-7555	1-800-248-8205	oncologysupply.com

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Neutropenia

RYTELO can cause neutropenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased neutrophils occurred in 72% of patients with MDS treated with RYTELO.

Monitor patients with Grade 3 or 4 neutropenia for infections, including sepsis. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

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Accessing RYTELO Through Specialty Distributors and Specialty Pharmacies

RYTELO can be dispensed and shipped directly to providers through the specialty pharmacies listed below.

Specialty Pharmacies

Authorized Pharmacy	NPI	Phone	Fax	Website
Biologics by McKesson	1487640314	1-800-850-4306	1-800-823-4506	biologics.mckesson.com
Onco360 Oncology Pharmacy (includes Puerto Rico)	1679618151	1-877-662-6633	1-877-662-6355	onco360.com

NPI=National Provider Identifier.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infusion-Related Reactions

RYTELO can cause infusion-related reactions. In the clinical trial, infusion-related reactions occurred in 8% of patients with MDS treated with RYTELO; Grade 3 or 4 infusion-related reactions occurred in 1.7%, including hypertensive crisis (0.8%). The most common infusion-related reaction was headache (4.2%). Infusion-related reactions usually occur during or shortly after the end of the infusion.

Premedicate patients at least 30 minutes prior to infusion with diphenhydramine and hydrocortisone as recommended and monitor patients for one hour following the infusion as recommended. Manage symptoms of infusion-related reactions with supportive care and infusion interruptions, decrease infusion rate, or permanently discontinue as recommended.

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Important Safety Information

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Embryo-Fetal Toxicity

RYTELO can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RYTELO and for 1 week after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 32% of patients who received RYTELO. Serious adverse reactions in >2% of patients included sepsis (4.2%), fracture (3.4%), cardiac failure (2.5%), and hemorrhage (2.5%). Fatal adverse reactions occurred in 0.8% of patients who received RYTELO, including sepsis (0.8%).

Most common adverse reactions (≥10% with a difference between arms of >5% compared to placebo), including laboratory abnormalities, were decreased platelets, decreased white blood cells, decreased neutrophils, increased AST, increased alkaline phosphatase, increased ALT, fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, COVID-19 infections, and headache.

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