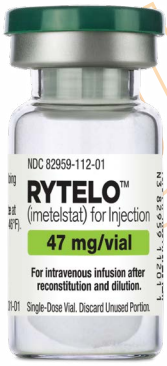
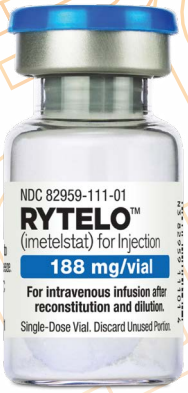
RYTELO™
(imetelstat) for Injection 47 mg 188 mg

ORDERING VIALS OF RYTELO



47 mg
NDC 82959-112-01



188 mg
NDC 82959-111-01

This information for prescribers of RYTELO is intended to help inform the number of RYTELO single-dose vials that may be clinically appropriate for product ordering.

This resource is provided for informational purposes only. It is not intended as medical advice or a substitute for a provider's independent clinical judgment. **Use of this information does not guarantee reimbursement. It is always the provider's responsibility to determine details specific to individual patients and to submit true and correct claims for the products and services rendered.** Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

NDC=National Drug Code.

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.

Calculating number of vials[1]

RYTELO is provided as a lyophilized powder in a single-dose vial in 2 sizes, 47 mg and 188 mg. The sample calculation shown below can be used to determine the number of vials that may be needed for a clinically appropriate individual patient dose.

Determine dose based on patient weight:

DOSE mg/kg × PATIENT WEIGHT kg = TOTAL mg

Calculate the number of RYTELO vials needed:

TOTAL mg ÷ 188 mg OR 47 mg = # of 188-mg vials AND/OR # of 47-mg vials

NOTE

It is recommended to use the appropriate combination of vial strengths to most closely match the intended dose based on the patient's weight. Please see Prescribing Information for additional detail.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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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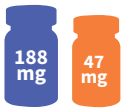
RYTELO™ (imetelstat) for Injection 47 mg 188 mg

Vial ordering for 7.1 mg/kg dose[2]



Patient weight (kg)	35-39	40-46	47-52	53-59	60-66	67-72	73-79
Dose range (mg)	248.5-276.9	284.0-326.6	333.7-369.2	376.3-418.9	426.0-468.6	475.7-511.2	518.3-560.9
Vials needed	1 (188 mg) + 2 (47 mg)	1 (188 mg) + 3 (47 mg)	2 (188 mg)	2 (188 mg) + 1 (47 mg)	2 (188 mg) + 2 (47 mg)	2 (188 mg) + 3 (47 mg)	3 (188 mg)
Patient weight (kg)	**80-86**	**87-92**	**93-99**	**100-105**	**106-112**	**113-119**	**120-125**
Dose range (mg)	568.0-610.6	617.7-653.2	660.3-702.9	710.0-745.5	752.6-795.2	802.3-844.9	852.0-887.5
Vials needed	3 (188 mg) + 1 (47 mg)	3 (188 mg) + 2 (47 mg)	3 (188 mg) + 3 (47 mg)	4 (188 mg)	4 (188 mg) + 1 (47 mg)	4 (188 mg) + 2 (47 mg)	4 (188 mg) + 3 (47 mg)
Patient weight (kg)	**126-132**	**133-138**	**139-145**	**146-152**	**153-158**	**159-165**	**166-167**
Dose range (mg)	894.6-937.2	944.3-979.8	986.9-1029.5	1036.6-1079.2	1086.3-1121.8	1128.9-1171.5	1178.6-1185.7
Vials needed	5 (188 mg)	5 (188 mg) + 1 (47 mg)	5 (188 mg) + 2 (47 mg)	5 (188 mg) + 3 (47 mg)	6 (188 mg)	6 (188 mg) + 1 (47 mg)	6 (188 mg) + 2 (47 mg)

The use of the information above does not guarantee reimbursement. It is the provider's responsibility to determine the number of vials needed for each individual patient and to submit accurate claims for the products and services rendered.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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.

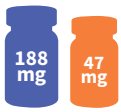
Premedicate patients at least 30 minutes prior to infusion with diphenhydramine and hydrocortisone as recommended and monitor patients for one hour following the infusion as recommended. Manage symptoms of infusion-related reactions with supportive care and infusion interruptions, decrease infusion rate,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

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

RYTELO™ (imetelstat) for Injection 47 mg 188 mg

Vial ordering for 5.6 mg/kg dose[2]

See the example below for the number of RYTELO vials that may be needed based on the 5.6 mg/kg dose and patient weight.



Patient weight (kg)	35-41	42-49	50-58	59-67	68-75	76-83	84-92
Dose range (mg)	196.0-229.6	235.2-274.4	280.0-324.8	330.4-375.2	380.8-420.0	425.6-464.8	470.4-515.2
Vials needed	1 1	1 2	1 3	2	2 1	2 2	2 3
Patient weight (kg)	**93-100**	**101-109**	**110-117**	**118-125**	**126-134**	**135-142**	**143-151**
Dose range (mg)	520.8-560.0	565.6-610.4	616.0-655.2	660.8-700.0	705.6-750.4	756.0-795.2	800.8-845.6
Vials needed	3	3 1	3 2	3 3	4	4 1	4 2
Patient weight (kg)	**152-159**	**160-167**					
Dose range (mg)	851.2-890.4	896.0-935.2					
Vials needed	4 3	5					

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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%).

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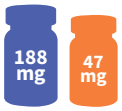
RYTELO™ (imetelstat) for Injection 47 mg 188 mg

Vial ordering for 4.4 mg/kg dose[2]

See the example below for the number of RYTELO vials that may be needed based on the 4.4 mg/kg dose and patient weight.



Patient weight (kg)	35-42	43-53	54-64	65-74	75-85	86-96	97-106
Dose range (mg)	154.0-184.8	189.2-233.2	237.6-281.6	286.0-325.6	330.0-374.0	378.4-422.4	426.8-466.4
Vials needed	1	1 1	1 2	1 3	2	2 1	2 2
Patient weight (kg)	**107-117**	**118-128**	**129-138**	**139-149**	**150-160**	**161-167**	
Dose range (mg)	470.8-514.8	519.2-563.2	567.6-607.2	611.6-655.6	660.0-704.0	708.4-734.8	
Vials needed	2 3	3	3 1	3 2	3 3	4	

The use of the information above does not guarantee reimbursement. It is the provider's responsibility to determine the number of vials needed for each individual patient and to submit accurate claims for the products and services rendered.

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS (cont'd)

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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RYTELO™ (imetelstat) for Injection 47 mg 188 mg

Important Safety Information

WARNINGS AND PRECAUTIONS

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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.

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.

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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.

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.

Please see full Prescribing Information, including Medication Guide.

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Notes

References

1. RYTELO. Prescribing information. Geron Corp.; 2024. **2.** Data on file. Geron Corp.

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