

Learn about **RYTELO** treatment

In this guide, you will find important treatment information for both patients and their caregivers.

Always talk to your doctor to discuss what's best for you.

Not actual patients.



What is RYTELO?

RYTELO (imetelstat) is a prescription medicine used to treat a condition called low- to intermediate-1 risk myelodysplastic syndromes (MDS) in adults:

- with anemia (low red blood cell counts) who need blood transfusions of 4 or more red blood cell units over 8 weeks
- and**
- who have not responded to, have stopped responding to, or cannot be treated with medicines called erythropoiesis-stimulating agents (ESAs).

It is not known if RYTELO is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before you receive RYTELO, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. RYTELO may harm your unborn baby and may cause loss of pregnancy (miscarriage). Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with RYTELO.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

RYTELO™ (imetelstat) works differently than other treatment options

- RYTELO works on a part of the cell that affects an enzyme called **telomerase**, which is often more active in abnormal MDS cells
- In nonclinical studies (studies in laboratories, not in humans), **RYTELO helped to stop these abnormal MDS cells from multiplying**

Talk to your doctor to learn more about RYTELO and whether it may be right for you.

MDS, myelodysplastic syndromes.

IMPORTANT SAFETY INFORMATION (cont'd)

Before you receive RYTELO, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

Females who are able to become pregnant:

- Your healthcare provider will perform a pregnancy test before you are given RYTELO.
- You should use effective birth control (contraception) during treatment with RYTELO and for 1 week after your last dose.
- are breastfeeding or plan to breastfeed. It is not known if RYTELO passes into your breastmilk. Do not breastfeed during treatment with RYTELO and for 1 week after your last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

How is RYTELO given?

RYTELO is a 2-hour IV infusion that is given every 4 weeks

Below are some important details on how RYTELO is given:



**2-hour IV
infusion**



**Every
4 weeks**



Recommended **dose is based on body weight and blood test results**



To prevent or reduce possible reactions from the infusion, your doctor will give you **premedications at least 30 minutes before your IV infusion** and will **monitor you for side effects for at least 1 hour afterward**



Depending on your blood tests, your doctor **may adjust your dose or when your dose is given** (please see pages 6 and 7).
Side effects may require dose delay or dose changes

IV, intravenous.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).


(imelstat) for Injection ^{47 mg}_{188 mg}

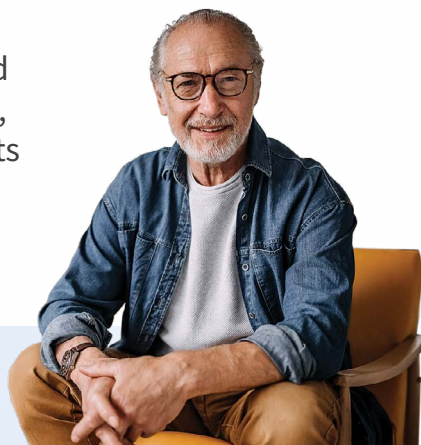
How was RYTELO™ (imetelstat) studied?

RYTELO was studied in the IMerge phase 3 clinical trial

In the IMerge trial, 178 patients with low- or intermediate-1 risk MDS were studied across 17 different countries.

The goal of this trial was to see whether 118 patients treated with RYTELO would need fewer red blood cell transfusions compared with the 60 patients who received treatment with no active medication (**placebo**).

Patients were selected for the IMerge trial if their previous MDS treatment with an erythropoiesis-stimulating agent (**ESA**) did not work for them or had stopped working, or if they were ineligible for an ESA. Patients could receive supportive care as needed, including red blood cell transfusions, platelet transfusions, and growth factors.



Not an actual patient.

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about RYTELO?

RYTELO may cause serious side effects, including:

- **Low platelet counts (thrombocytopenia).** Low platelet counts are common during treatment with RYTELO and can also be severe. Low platelet counts can increase your risk for bleeding. Your healthcare provider may give you platelet transfusions to reduce the risk of bleeding if you develop a low platelet count during treatment with RYTELO. Tell your healthcare provider right away if you develop any signs or symptoms of bleeding, including:
 - unusual bleeding or bruising
 - vomiting blood
 - bleeding that lasts a long time
 - blood in your stool or black tarry stool
 - nosebleeds

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

What were the results from the clinical trial?

The primary trial objective was to determine the number of RYTELO patients who reached 8 consecutive weeks or more without a red blood cell transfusion.

Nearly 40% (n=47 out of 118) of patients taking RYTELO required **ZERO** red blood cell transfusions for 8 consecutive weeks or more vs 15% (n=9 out of 60) of patients taking placebo

The secondary objective was to determine the number of RYTELO patients who reached 24 consecutive weeks or more without a red blood cell transfusion.

28% (n=33 out of 118) of patients taking RYTELO required* **ZERO** red blood cell transfusions for 24 consecutive weeks or more vs 3% (n=2 out of 60) of patients taking placebo

IMPORTANT SAFETY INFORMATION (cont'd)

What is the most important information I should know about RYTELO? (cont'd)

• **Low neutrophil counts (neutropenia).** Low counts of a type of white blood cell called neutrophils are common during treatment with RYTELO and can also be severe. Low neutrophil counts can increase your risk for infections, including serious infections and sepsis. Your healthcare provider may give you medicines before you start treatment to help prevent neutropenia and infections and may treat you with medicines if you develop these problems during treatment with RYTELO. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with RYTELO, including:

- fever
- shortness of breath or trouble breathing
- cough
- chills
- pain or burning when you urinate

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

 **RYTELO**[™]
(imelstat) for Injection 47 mg
188 mg

What are the possible side effects with RYTELO™ (imetelstat)?

Patients may experience cytopenias

Low numbers of different types of blood cells, also known as **cytopenias**, were the most frequent side effect experienced from RYTELO treatment.



Low platelet counts (**thrombocytopenia**): Low platelet counts are common during treatment with RYTELO and can also be severe. Low platelet counts can increase your risk for bleeding. Your healthcare provider may give you platelet transfusions to reduce the risk of bleeding if you develop a low platelet count during treatment with RYTELO.



Low neutrophil counts (**neutropenia**): Low counts of a type of white blood cell called neutrophils are common during treatment with RYTELO and can also be severe. Low neutrophil counts can increase your risk for infections, including serious infections and sepsis. Your healthcare provider may give you medicines before you start treatment to help prevent neutropenia and infections and may treat you with medicines if you develop these problems during treatment with RYTELO.

Patients who have low platelet or low neutrophil counts may not always have the symptoms described above, so your doctor will do regular bloodwork to test for them.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

RYTELO can cause infusion-related reactions (IRRs) during or after your infusion, including a severe sudden increase in blood pressure called hypertensive crisis

Tell your healthcare provider if you develop any signs or symptoms of IRRs, including:

- Stomach pain
- Joint pain
- Weakness and tiredness
- Back and bone pain
- Diarrhea
- Redness
- Headache
- High blood pressure
- Not feeling well
- Chest pain that is not related to your heart
- Itching
- Hives

Most common side effects included:



Low platelet counts



Low white blood cell counts



Low neutrophil counts



Liver enzyme changes



Tiredness



Slower blood clotting



Joint/bone/muscle pain



COVID-19 infections



Headache



Remember, it is important to always keep your doctor informed about how you are feeling on treatment. Talk to your doctor about any side effects that you may be experiencing. Your doctor will continue to monitor side effects throughout your treatment and will make any adjustments as needed.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

**RYTELO**TM
(imelstat) for Injection 47 mg
188 mg



Important Safety Information

Before you receive RYTELO, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. RYTELO may harm your unborn baby and may cause loss of pregnancy (miscarriage). Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with RYTELO.

Females who are able to become pregnant:

- Your healthcare provider will perform a pregnancy test before you are given RYTELO.
 - You should use effective birth control (contraception) during treatment with RYTELO and for 1 week after your last dose.
- are breastfeeding or plan to breastfeed. It is not known if RYTELO passes into your breastmilk. Do not breastfeed during treatment with RYTELO and for 1 week after your last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the counter medicines, vitamins, and herbal supplements.

What is the most important information I should know about RYTELO?

RYTELO may cause serious side effects, including:

- **Low platelet counts (thrombocytopenia).** Low platelet counts are common during treatment with RYTELO and can also be severe. Low platelet counts can increase your risk for bleeding. Your healthcare provider may give you platelet transfusions to reduce the risk of bleeding if you develop a low platelet count during treatment with RYTELO. Tell your healthcare provider right away if you develop any signs or symptoms of bleeding, including:

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

**RYTELO™**
(imeteIstat) for Injection 47 mg
188 mg

Important Safety Information (cont'd)

- unusual bleeding or bruising
 - bleeding that lasts a long time
 - nosebleeds
 - vomiting blood
 - blood in your stool or black tarry stool
- **Low neutrophil counts (neutropenia).** Low counts of a type of white blood cell called neutrophils are common during treatment with RYTELO and can also be severe. Low neutrophil counts can increase your risk for infections, including serious infections and sepsis. Your healthcare provider may give you medicines before you start treatment to help prevent neutropenia and infections and may treat you with medicines if you develop these problems during treatment with RYTELO. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with RYTELO, including:
 - fever
 - shortness of breath or trouble breathing
 - cough
 - chills
 - pain or burning when you urinate

Your healthcare provider will do blood tests to check your platelet and neutrophil counts before starting treatment with RYTELO, weekly for the first 2 cycles of treatment, before you receive each additional cycle, and as needed during your treatment.

Your healthcare provider may delay your next treatment, decrease your dose, or stop treatment with RYTELO if you develop thrombocytopenia or neutropenia during treatment.

What are the possible side effects of RYTELO?

RYTELO may cause serious side effects, including:

- See “What is the most important information I should know about RYTELO?”

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

**RYTELO**TM
(imelstat) for Injection 47 mg
188 mg

Important Safety Information (cont'd)

What are the possible side effects of RYTELO? (cont'd)

RYTELO may cause serious side effects, including: (cont'd)

- **Infusion-related reactions.** RYTELO can cause infusion-related reactions during or after your infusion that can be severe, including a severe sudden increase in blood pressure called hypertensive crisis. Your healthcare provider will give you medicines before each RYTELO infusion to help prevent or lessen infusion-related reactions and will watch you for at least 1 hour after your infusion. If you develop infusion-related reactions, your healthcare provider may infuse RYTELO more slowly, temporarily stop, or permanently stop your treatment. Tell your healthcare provider if you develop any signs or symptoms of infusion-related reactions, including:

- stomach pain
- joint pain
- weakness and tiredness
- back and bone pain
- diarrhea
- redness
- headache
- high blood pressure
- not feeling well
- chest pain that is not related to your heart
- itching
- hives

The most common side effects of RYTELO include:

- decreased platelet counts
- decreased white blood cell counts
- decreased neutrophil counts
- increased liver enzymes (AST, alkaline phosphatase, and ALT)
- tiredness
- longer than usual blood clotting times
- joint, bone and muscle pain
- Covid-19 infections
- headache

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

**RYTELO™**
(imelstat) for Injection 47 mg
188 mg

Important Safety Information (cont'd)

These are not all of the possible side effects of RYTELO. Call your doctor for more information and medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).

Discover the REACH4RYTELO™ support program

REACH4RYTELO provides financial assistance for eligible patients



To learn more about RYTELO, visit [RYTELO.com](https://www.rytelocom.com).

Call **1-844-4RYTELO** to get support today!

Monday to Friday 8:00 AM - 8:00 PM ET (Except major holidays)

To enroll in REACH4RYTELO, you must be a US resident with a valid prescription for RYTELO. Additional eligibility requirements apply for financial assistance programs.

What is RYTELO?

RYTELO (imetelstat) is a prescription medicine used to treat a condition called low- to intermediate-1 risk myelodysplastic syndromes (MDS) in adults:

- with anemia (low red blood cell counts) who need blood transfusions of 4 or more red blood cell units over 8 weeks
- and**
- who have not responded to, have stopped responding to, or cannot be treated with medicines called erythropoiesis-stimulating agents (ESAs).

It is not known if RYTELO is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Before you receive RYTELO, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. RYTELO may harm your unborn baby and may cause loss of pregnancy (miscarriage). Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with RYTELO.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including [Medication Guide](#).



C-US-RYT-IM-0122 September 2024 © 2024 Geron Corp. All rights reserved. GERON, GERON logo, RYTELO, RYTELO logo, REACH4RYTELO, and REACH4RYTELO logo are trademarks of Geron Corporation.


(imetelstat) for Injection 47 mg
188 mg