**MEDICATION GUIDE**
**RYTELO™ (ri-TEL-o)**
**(imetelstat)**
**for injection, for intravenous use**

**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
  - 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.

See "**What are the possible side effects of RYTELO?**" for more information about side effects.

**What is RYTELO?**
RYTELO 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 other medicines called erythropoiesis-stimulating agents (ESAs).

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

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

**How will I receive RYTELO?**

- RYTELO will be given as an intravenous infusion into your vein over a period of 2 hours by your healthcare provider.
- RYTELO is usually given every 4 weeks.
- Your healthcare provider will prescribe RYTELO in a dose that is right for you and may change your dose, change your dosing schedule, or stop treatment depending on how you respond to RYTELO.
- Your healthcare provider will do certain blood tests during treatment with RYTELO to check for side effects and to see how well you respond to treatment.
- Your healthcare provider will decide how long you will continue treatment with RYTELO.

**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?**"
- **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

RYTELO may cause fertility problems in females. This could affect your ability to get pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of RYTELO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of RYTELO.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about RYTELO that is written for health professionals.

**What are the ingredients in RYTELO?**
**Active ingredient:** imetelstat
**Inactive ingredients:**

- 47 mg: sodium carbonate anhydrous or hydrochloric acid may be added during manufacturing to adjust the pH
- 188 mg: sodium carbonate monohydrate or hydrochloric acid may be added during manufacturing to adjust the pH

Manufactured for: Geron Corporation, 919 E. Hillsdale Blvd., Suite 250, Foster City, CA 94404
Manufactured by (47 mg vials):
Patheon Italia, S.p.A, 2° Trav. SX Via Morolense, 5, 03013 Ferentino (FR), Italy
Manufactured by (188 mg vials):
Catalent Indiana, LLC, 1300 S Patterson Drive, Bloomington, IN 47403
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For more information about RYTELO, go to www.RYTELO.com or call 1-866-471-0921.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 6/2024