



REZLIDHIA[®]
(olutasidenib) 150 mg
capsules

GETTING STARTED

Get to know REZLIDHIA and what you can expect with your AML treatment.

What is REZLIDHIA?

REZLIDHIA is a prescription medicine used to treat adults with acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (IDH1) mutation when the disease has come back or has not improved after previous treatment(s).

Your healthcare provider will perform a test to make sure that REZLIDHIA is right for you.

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

IMPORTANT SAFETY INFORMATION

REZLIDHIA may cause serious side effects including differentiation syndrome. Differentiation syndrome is a condition that affects your blood cells and may be life-threatening or lead to death. Differentiation syndrome in adults with acute myeloid leukemia (AML) has occurred as early as 1 day and up to 18 months after starting REZLIDHIA. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any symptoms of differentiation syndrome during treatment with REZLIDHIA.

Please see Important Safety Information throughout and accompanying Full Prescribing Information, including Boxed WARNING and Medication Guide.

WHAT IS MOST IMPORTANT TO KNOW ABOUT REZLIDHIA BEFORE STARTING TREATMENT?

REZLIDHIA MAY CAUSE DIFFERENTIATION SYNDROME.

Differentiation syndrome is a condition that affects your blood cells and may be life-threatening or lead to death. Differentiation syndrome in adults with acute myeloid leukemia (AML) has occurred as early as 1 day and up to 18 months after starting REZLIDHIA.



Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome while taking REZLIDHIA:

- Fever
- Cough
- Trouble breathing
- Decreased urination
- Dizziness or lightheadedness
- Weight gain
- Swelling in your arms or legs

If you develop signs and symptoms of differentiation syndrome, your healthcare provider may treat you with a corticosteroid medicine or a medicine called hydroxyurea and may monitor you in the hospital.

REZLIDHIA MAY CAUSE LIVER PROBLEMS.

Changes in liver function tests are common during treatment with REZLIDHIA and can be serious. Your healthcare provider will do blood tests to check your liver function before and during treatment with REZLIDHIA.

Tell your healthcare provider right away if you develop any of the following symptoms of liver problems during treatment with REZLIDHIA:

- Yellowing of your skin or the white part of your eyes (jaundice)
- Dark “tea-colored” urine
- Loss of appetite
- Pain on the upper right side of your stomach area
- Feeling very tired or weak

If you develop any of the symptoms above, your healthcare provider may treat you with prescription medications.

HOW DO I TAKE REZLIDHIA?

REZLIDHIA SHOULD BE TAKEN:



By mouth



On an empty stomach



2 times a day

- **DO** take 1 capsule of REZLIDHIA twice a day around the same time each day, about 12 hours apart
- **DO** take REZLIDHIA 1 hour before, OR 2 hours after a meal
- **DO** swallow REZLIDHIA capsules whole
- **DO NOT** take 2 capsules within 8 hours
- **DO NOT** break, open, or chew REZLIDHIA
- **DO NOT** stop or change your dose without talking to your healthcare provider

Always take REZLIDHIA exactly as your healthcare provider tells you to.

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WHAT IF I MISS A DOSE?

IF YOU MISS A DOSE OF REZLIDHIA OR DID NOT TAKE IT AT THE USUAL TIME:

- Take your dose as soon as possible and at least 8 hours before your next dose
- Return to your normal schedule the following day

IF YOU VOMIT AFTER TAKING A DOSE OF REZLIDHIA:

- Do not take another dose
- Take your next dose at your usual time

Between doses, store REZLIDHIA at room temperature, from 68°F to 77°F (20°C to 25°C)



Not actual size.



Talk to your healthcare provider if you still have questions about treatment with REZLIDHIA.

After you begin treatment, be sure to tell them about any side effects or changes in your condition so they can adjust your treatment plan to best suit your needs.

POSSIBLE SIDE EFFECTS AND WHAT TO TELL YOUR HEALTHCARE PROVIDER BEFORE STARTING REZLIDHIA

THE MOST COMMON SIDE EFFECTS OF REZLIDHIA IN ADULTS WITH AML INCLUDE:

- Abnormal liver function tests
- Nausea
- Feeling tired or unwell
- Joint pain
- Constipation
- Shortness of breath
- Fever
- Rash
- Mouth sores
- Diarrhea
- Changes in certain blood tests

Tell your healthcare provider if you have any nausea, constipation, diarrhea, vomiting, stomach pain or mouth sores.

Your healthcare provider will do blood tests before you start and during treatment with REZLIDHIA. Your healthcare provider may decrease, temporarily hold, or permanently stop your treatment with REZLIDHIA if you develop certain side effects. These are not all the possible side effects of REZLIDHIA.

BEFORE TAKING REZLIDHIA, TELL YOUR HEALTHCARE PROVIDER ABOUT ALL OF YOUR MEDICAL CONDITIONS, INCLUDING IF YOU:

- have liver problems.
- are pregnant or plan to become pregnant. REZLIDHIA may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if REZLIDHIA passes into your breast milk. Do not breastfeed during your treatment with REZLIDHIA and for 2 weeks after your last dose of REZLIDHIA.

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

**Call your healthcare provider for medical advice about side effects.
You may report side effects to FDA at 1-800-FDA-1088.**

WHAT TO KNOW ABOUT YOUR TREATMENT

- 1 REZLIDHIA is for adults with IDH1+ AML** whose disease has come back or hasn't responded to treatment
- 2 REZLIDHIA is taken by mouth, twice a day, on an empty stomach.** Your healthcare provider will adjust your treatment as needed
- 3 Your healthcare provider will monitor your condition** for signs of differentiation syndrome, liver problems, and possible serious effects of treatment
- 4 There are other possible side effects** such as nausea, constipation, diarrhea, and vomiting. Tell your healthcare provider about any health conditions and medications before starting treatment
- 5 Always take REZLIDHIA exactly as instructed**

To learn more, visit REZLIDHIA.com

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South San Francisco, CA 94080

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