

## Olutasidenib (Rezlidhia)

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### About This Medicine

OLUTASIDENIB (oh LOO ta SID e nib) treats leukemia. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- A rapid increase in your white blood cells
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Fever
- Tiredness
- General discomfort, a feeling of being unwell
- Pain in the joints
- Electrolyte changes
- An increase in uric acid in the blood
- Changes in your liver and pancreas function
- Changes in your kidney function
- Trouble breathing
- Rash

**Note:** Each of the side effects above was reported in 20% or greater of people treated with olutasidenib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- A serious syndrome may happen with the use of this medicine that is known as differentiation syndrome, which can be life-threatening. It can cause fever, weight gain, swelling, and breathing problems. **Immediately report any of these symptoms to your care team.**
- Severe changes in your liver function

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

## How to Take Your Medicine

- Swallow the medicine whole, on an empty stomach, at least 1 hour before or 2 hours after a meal. Do not chew, break, or open capsules.
- Take this medicine at approximately the same time each day.
- **Missed dose:** If you miss a dose, take it as soon as you think about it **ONLY** if your next dose is due in more than 8 hours. If your next dose is due in **LESS** than 8 hours, then skip the missed dose and take your next dose at the regular time. Do not replace a vomited dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

## Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.



- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicine that can lessen or stop diarrhea and/or constipation.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

## Food and Medicine Interactions

- There are no known interactions of olutasidenib with food, however this medicine should be taken on an empty stomach.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with olutasidenib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

## When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
  - Chills
  - Wheezing and/or trouble breathing
  - Tiredness that interferes with your daily activities
  - Pain in your mouth or throat that makes it hard to eat or drink
  - Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
  - Throwing up more than 3 times a day
  - No bowel movement in 3 days or when you feel uncomfortable
  - Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
  - Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
  - Signs of differentiation syndrome such as fever, weight gain, swelling, and/or trouble breathing.
- Immediately report any of these symptoms to your healthcare provider.**
- Pain that does not go away, or is not relieved by prescribed medicines
  - Decreased or very dark urine

- New rash and/or itching
- Rash that is not relieved by prescribed medicines

## Reproduction Warnings

- **Pregnancy warning:** Talk with your care team if you are pregnant or planning to become pregnant while taking this medicine. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 2 weeks after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

Revised February 2025

