

Entrectinib (Rozlytrek)

About This Medicine

ENTRECTINIB (en TREK ti nib) treats some types of cancer. 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

- Blurred vision or other changes in eyesight
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Tiredness
- Fever
- Swelling of the hands, feet, or any other part of the body
- Weight gain
- Changes in the way food and drinks taste
- Feeling dizzy
- Numbness, tingling, or a sensation of pins and needles in your arms, hands, legs, or feet
- Cognitive disorders such as confusion, hallucination, memory loss, and/or difficulty speaking
- Muscle and joint pain
- Cough
- Trouble breathing

Note: Each of the side effects above was reported in 20% or greater of people treated with entrectinib. 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



- Changes in your heart function such as abnormal electrocardiogram (EKG/ECG) and congestive heart failure – your heart is not pumping blood as well as it should be, and fluid can build up in your body.
- Increased risk of bone fractures
- Increased uric acid in your blood, which may be caused by tumor lysis syndrome. This medicine may act on the cancer cells very quickly. This may affect how your kidneys work and can be life-threatening.
- Severe changes in your liver function
- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, have hallucinations (see or hear things that are not there), trouble understanding or speaking and eyesight changes. You may have changes in mood or have trouble sleeping. **If you start to have any of these symptoms let your care team know right away.**
- Blurred vision or other changes in eyesight such as double vision, sensitivity to light (photosensitivity). Photosensitivity means that you may become more sensitive to the sun and/or light. Your eyes may water more, mostly in bright light.

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

Important Information

- This medicine may impair your ability to drive or use machinery. Use caution and tell your care team about any precautions you may need to take.

How to Take Your Medicine

- **Capsules:** Swallow the medicine whole with or without food. Do not crush or chew the capsules.
- **Capsules prepared for suspension:** Carefully open the prescribed number of capsules and pour the contents into room temperature water or milk. Your care team or pharmacist will tell you how much water or milk to use, how much suspension to take and give you a measuring cup or oral syringe. Let the suspension sit for 15 minutes before swallowing. Drink water after taking the suspension to make sure you have swallowed all of the medicine.
- If you cannot swallow and have a gastric or nasogastric tube, you can take the suspension through the feeding tube. Talk with your care team or pharmacist about how to take your medicine through your feeding tube.
- You should take the suspension after you prepare it, but it can be stored for up to 2 hours at room temperature below 86°F (30°C). Throw away any unused suspension if not used within 2 hours of preparation.
- **Oral pellets:** Sprinkle the prescribed number of packets of pellets on 1 or more spoonfuls of a soft food such as applesauce, yogurt, or pudding, and take within 20 minutes of sprinkling the pellets on the soft food. Do not crush or chew the pellets to avoid a bitter taste. Drink water after taking the prepared pellets to make sure you have swallowed all of the medicine.
- Do not use the pellets to make a suspension. Do not use the pellets with a gastric or nasogastric tube.



- **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 12 hours. If your next dose is due in less than 12 hours, then skip the missed dose and take your next dose at the regular time.
- If you vomit immediately after taking a dose, repeat the dose again.
- **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:**
- **Capsules and pellets:** Store this medicine in the original container at room temperature. Keep lid tightly closed. Protect from moisture. 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
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- If you are dizzy, get up slowly after sitting or lying.
- Drink enough fluids to keep your urine pale yellow.
- 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 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).
- 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.
- Taking good care of your mouth may help food taste better and improve your appetite.
- Ask your care team about medicines that are available to help stop or lessen constipation and/or diarrhea.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.



- Wear dark sunglasses when in the sun or bright lights.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of entrectinib in your body which could make side effects worse.
- Check with your care team or pharmacist 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 entrectinib. Also, check with your care team or pharmacist 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
- Blurred vision or other changes in eyesight
- Sensitivity to light
- Feeling dizzy and/or lightheaded
- Tiredness and weakness that interferes with your daily activities
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Extreme tiredness, agitation, or confusion
- Hallucinations
- Trouble understanding or speaking
- Trouble sleeping
- Wheezing and/or trouble breathing
- Cough that is bothersome
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Changes in the way food and drink taste that is causing a loss of appetite
- 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
- Swelling of the hands, feet, or any other part of the body
- Numbness, tingling, pins and needles, or pain in your arms, hands, legs, or feet
- Weight gain of 5 pounds in one week (fluid retention)
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures
- 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



- Pain that does not go away or is not relieved by prescribed medicine

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for at least 5 weeks after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 3 months after the last dose. 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 7 days after the last dose.
- **Fertility warning:** The effect of this medicine on fertility is not known. If you plan to have children, talk with your care team.

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