



Entrectinib (Rozlytrek™)

About This Drug

Entrectinib is used to treat cancer. It is given orally (by mouth).

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 your legs, ankles and/or feet
- 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 and trouble breathing

Note: Each of the side effects above was reported in 20% or greater of patients treated with entrectinib. Not all possible side effects are included above.

Warnings and Precautions

- Changes in your heart function such as abnormal EKG and congestive heart failure – your heart has less ability to pump blood properly.
- Increased risk of bone fractures.
- Increased uric acid in your blood, which may be caused by tumor lysis syndrome. This drug 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 doctor 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 medical team.

Important Information

- This drug may impair your ability to drive or use machinery. Use caution and tell your nurse or doctor if you feel dizzy, very sleepy, and/or experience any changes in your vision.

How to Take Your Medication

- Swallow the medicine whole with or without food. Do not open, crush, chew or dissolve the capsules.
- **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.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container below 86°F.
- **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 medication 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 nurse or your doctor 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. 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 plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 nurse or doctor 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 doctor or nurse 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 doctor or nurse before you use enemas, laxatives, or suppositories.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse 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.
- To help with sensitivity to light, wear dark sun glasses when in the sun or bright lights.

Food and Drug 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 doctor or pharmacist about all other prescription medicines and dietary supplements you are taking before starting this medicine as there are known drug interactions with entrectinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplement to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking entrectinib as this may lower the levels of the drug in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse 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
- Feeling dizzy 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
- Wheezing or trouble breathing
- Coughing up yellow, green, or bloody mucus
- 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
- Swelling of arms, hands, legs and/or feet
- Weight gain of 5 pounds in one week (fluid retention)
- Numbness, tingling, pins and needles, or pain your arms, hands, legs or feet
- 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, bad stomach pain, 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
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 5 weeks after treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 3 months after your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 7 days after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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