Entrectinib (Rozlytrek™)

Pronounced: en TREK ti nib

Classification: Kinase Inhibitor

About Entrectinib (Rozlytrek™)

Entrectinib is a kinase inhibitor. A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells. This medication only works in tumors with certain neurotrophic receptor kinase (NTRK) genes. Your oncology team will test your tumor for this abnormality, which must be present in order to receive the medication.

How to Take Entrectinib

Entrectinib is a capsule taken orally once daily with or without food. Swallow the capsules whole: do not open, crush, chew or dissolve them. If you miss a dose, take it as soon as you remember. If your next dose is due within the next 12 hours, skip the missed dose and take the next dose at your usual time. If you vomit after taking this medication, you can take another dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, verapamil, ketoconazole, rifampin, phenytoin, St. John’s wort, and modafanil. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). The oral liquid solution should be kept in the refrigerator. This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Entrectinib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.
**Possible Side Effects of Entrectinib**

There are a number of things you can do to manage the side effects of entrectinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Kidney Problems**

This medication can cause kidney problems, including an increased creatinine level and elevated uric acid levels, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Constipation**

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Appetite/Taste Changes and Weight Gain**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

**Peripheral Edema**

Peripheral edema is swelling of the extremities caused by retention of fluid. It can cause swelling of the hands, arms, legs, ankles and feet. The swelling can become uncomfortable. Notify your oncology care team if you are experiencing any new or worsening swelling.

**Low White Blood Cell Count (Leukopenia or Neutropenia)**
White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F / 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

**Tips to preventing infection:**

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Diarrhea**

Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Abnormal Touch Sensation (Dysthesia)**

Entrectinib can cause a change in your touch sensation, or how things feel when you touch them. Symptoms include an itchy, burning sensation on or under the skin and unexplained pain that travels to other parts of your body. Tell your healthcare team if you are experiencing these symptoms while taking this medication.

**Cognitive Problems/ Dizziness**

This medication can cause changes to your mood, thoughts and senses. Symptoms include fainting, tiredness, blurring visions, memory loss, confusion, depressions, and sleep changes. It can also cause dizziness. Report any cognitive changes to your healthcare provider. You should not operate machinery or drive a car until you know how entrectinib affects you.

**Electrolyte Abnormalities**

This medication can affect the normal levels of electrolytes (potassium, phosphorus, sodium, calcium, etc) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Muscle or Joint Pain/Aches and Headache**

Your healthcare provider can recommend medications and other strategies to help relieve pain.

**Eye Concerns**

While receiving entrectinib some patients may experience changes in your eyesight. Notify your healthcare team if you develop any double vision, blurry vision, new or increased floaters, or if the light hurts your eyes.
**Less common but important side effects include:**

- **Heart problems:** This medication can cause or worsen pre-existing congestive heart failure. Notify your healthcare provider if you have sudden weight gain or swelling in the ankles or legs. If you develop chest pain or pressure, pain in the left arm, back, or jaw, sweating, shortness of breath, clammy skin, nausea, dizziness or lightheadedness, call 911 or go to the nearest emergency room.

- **QT prolongation:** This medication can cause slow or abnormal heartbeats or an abnormal heart rhythm called QT prolongation. Notify your oncology care team right away if you feel abnormal heartbeats or if you feel dizzy or faint.

- **Skeletal fractures:** This medication can increase your risk for broken bones, particularly of the hip and leg. You may be more at risk of fracture after a fall or trauma while receiving this medication. Report any pain, or changes in your ability to walk to your healthcare team.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Women will be asked to take a pregnancy test prior to receiving this medication. Effective birth control is necessary during treatment and for 5 weeks after the last dose for women and 3 months after the last dose for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while receiving this medication and for 7 days after the final dose.