

ORAL CHEMOTHERAPY EDUCATION



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ENTRECTINIB

Name of your medication

Generic name — entrectinib (en-TREK-tih-nib)
Brand name — Rozlytrek® (roz-LY-trek)

Common uses

Entrectinib is used to treat metastatic non-small cell lung cancer (NSCLC) that has a mutation of the ROS-1 gene, as well as to treat cancers that have a neurotrophic tyrosine kinase (NTRK) gene mutation.

Entrectinib may also be used for other treatments.

Dose and schedule

Taking entrectinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual adult dose of entrectinib is 600 milligrams (600 mg) to be taken by mouth at a scheduled time once a day.
- Entrectinib can be taken with or without food, but at the same time each day.
- Entrectinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow entrectinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of entrectinib, take it as soon as you remember. If your next dose is due within 12 hours, skip the missed dose. **Do not** take an extra dose or two doses at one time.

Drug and food interactions

- Entrectinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice may interact with entrectinib; avoid eating or drinking this during treatment with entrectinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle entrectinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store entrectinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep entrectinib out of reach of children and pets.
- Leave entrectinib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give entrectinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the entrectinib to you, they also need to follow these steps.

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1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the entrectinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder is used, contact your care team before using. The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder). When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.

Side Effects of Entrectinib

Below are common side effects that have been known to happen in about one-third or more of patients taking entrectinib; these are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Changes in kidney function	<p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Decreased amount of urination • Unusual swelling in your legs and feet
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations

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Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High uric acid levels • High sodium levels • Low calcium levels • Low phosphorus levels • High potassium levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs and feet • Red- or brown-colored urine
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating cars or machinery if you feel too tired.
<p>Constipation</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Stay active and exercise, if possible. • Eat foods high in fiber like raw fruits and vegetables. <p>Contact your care provider if you have not had a bowel movement in three or more days.</p> <p>Your care provider may recommend over-the-counter medications to help with your constipation. A daily stool softener such as docusate (Colace®) and/or a laxative such as senna (Senakot®) may be helpful. If these do not help within 48 hours, tell your provider.</p>
<p>Taste changes</p>	<p>Some people experience a metallic or bitter taste in their mouth. To help with taste changes, try the following:</p> <ul style="list-style-type: none"> • Choose and prepare foods that look and smell good to you. • Use plastic utensils if food tastes like metal. • Flavor foods with spices to change taste. • Suck on mints or chew gum to mask taste. • Brush teeth before and after eating with a soft bristle toothbrush. • Avoid smoking. <p>Notify your doctor if you are having trouble eating or are losing weight.</p>

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Possible Side Effect	Management
Changes in liver function	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following.</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising
Decreased white blood cells (WBCs) and increased risk for infection	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
Dizziness	<p>You may notice a lightheaded, weak, or unsteady feeling while you are on this medication. Use caution when driving and operating machinery.</p> <p>Let your provider know if this feeling occurs.</p>
Fluid retention or swelling (edema)	<ul style="list-style-type: none"> • Do not stand for long periods of time. • Keep your legs elevated when sitting or lying down. • Try to not eat salty foods, which can increase swelling. • Avoid tight-fitting clothing and shoes. • Weigh yourself daily. • Take any medications as prescribed to decrease fluid retention. <p>Contact your care team if you notice:</p> <ul style="list-style-type: none"> • Swelling in the hands, feet, or legs • You are short of breath. • You have gained 5 pounds or more in one week.

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Possible Side Effect	Management
Diarrhea (loose and/or urgent bowel movements)	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
Nausea or vomiting	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication that can help with the nausea or vomiting.</p>
Cough or shortness of breath	<p>A cough that does not produce any mucous or congestion relief (dry cough) may occur while taking this medication. If you experience any breathing problems or shortness of breath, notify your care provider immediately. This may be a serious side effect of the medication.</p>

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Serious side effects

- Birth defects: Entrectinib can cause serious birth defects. Do not take entrectinib if you are pregnant or think you might be pregnant.
- Heart failure: Entrectinib can cause heart failure. Contact your care team right away if you are having any swelling or shortness of breath.
- Central nervous system (CNS) side effects: Entrectinib may cause dizziness, changes in your mood, or confusion, hallucinations, problems with concentration, attention, memory, and sleep, and it may affect how you think. Speak with your care team if you notice any of these symptoms.
- Bone fractures: Entrectinib can cause bones and muscles to weaken and may increase your risk for falls and broken bones. Your doctor may prescribe a medication to decrease your risk of broken bones.
- QT prolongation: Entrectinib may cause a condition called QT or QTc prolongation, which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life-threatening. Tell your care team right away if you feel faint, lightheaded, or dizzy, or if you feel your heart beating irregularly or fast while taking entrectinib.
- Vision problems: Entrectinib may cause changes to your vision. Tell your care team right away if you have any loss of vision or changes in your eyesight, such as double vision, blurry vision, new or increased floaters, seeing flashes of light, or light hurting your eyes.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since entrectinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take entrectinib, it is important to adhere to the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or entrectinib with soap and water.

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- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking entrectinib.
 - Women of childbearing age and potential should use effective contraception during therapy and for a minimum of 5 weeks after the last dose of entrectinib.
 - Men who have female partners who can become pregnant should use effective contraception during therapy and for a minimum of 3 months after the last dose of entrectinib.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking entrectinib and for 7 days after the last dose of entrectinib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.

Obtaining medication

- Talk with your care provider about the process for obtaining your entrectinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.rozlytrek.com>

Product prescribing information: https://www.gene.com/download/pdf/rozlytrek_prescribing.pdf

Product resources: <https://www.rozlytrek.com/hcp/resources/financial-assistance-for-patients.html>

Updated – September 5, 2023

Additional instructions

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Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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