

PATIENT INFORMATION

ROZLYTREK® (roz lye' trek)
(entrectinib)
capsules

ROZLYTREK® (roz lye' trek)
(entrectinib)
oral pellets

What is the most important information I should know about ROZLYTREK?

ROZLYTREK may cause serious side effects, including:

- **Congestive heart failure.** ROZLYTREK may cause congestive heart failure or make the congestive heart failure that you already have worse. Your healthcare provider will do tests before your treatment and may do tests during your treatment with ROZLYTREK to check your heart function. Tell your healthcare provider right away if you have any of the following signs and symptoms of congestive heart failure:
 - persistent coughing or wheezing
 - trouble breathing when lying down
 - sudden weight gain
 - increasing shortness of breath
 - tiredness, weakness, or fatigue
 - swelling in ankles, feet, or legs
- **Central nervous system (CNS) effects.** ROZLYTREK may cause dizziness, changes in your mood, or may affect how you think and cause confusion, hallucinations, and problems with concentration, attention, memory, speaking, understanding what you hear or read, and sleep. Tell your healthcare provider right away if you have any of these symptoms.
- **Bone fractures.** ROZLYTREK may increase your risk for bone fractures. Bone fractures may happen with or without a fall or other injury. Tell your healthcare provider if you develop pain, changes in movement, or bone abnormalities.
- **Liver problems (hepatotoxicity).** Your healthcare provider will do blood tests to check your liver function during treatment with ROZLYTREK. Tell your healthcare provider right away if you develop any of the following symptoms of liver problems:
 - loss of appetite
 - nausea or vomiting
 - pain in your upper right stomach area
 - yellowing of your skin or the white part of your eyes
 - dark urine
- **Increased uric acid level in your blood (hyperuricemia).** ROZLYTREK may cause too much uric acid in your blood. Your healthcare provider will do tests before and during your treatment with ROZLYTREK to check the uric acid level in your blood. Your healthcare provider may prescribe medications if you have high blood uric acid levels. Tell your healthcare provider if you develop any of the following symptoms of hyperuricemia:
 - red, hot, tender, or swollen joints, especially in your big toe
 - pain in your stomach-area or sides
 - nausea or vomiting
 - pink or brown urine
- **Changes in the electrical activity of your heart called QT prolongation.** QT prolongation can cause irregular heartbeats that can be life-threatening. Your healthcare provider will do tests before and during your treatment with ROZLYTREK to check the electrical activity of your heart and your body salts (electrolytes). Tell your healthcare provider right away if you feel faint, lightheaded, dizzy, or feel your heart beating irregularly or fast during your treatment with ROZLYTREK. These may be symptoms related to QT prolongation.
- **Vision problems.** ROZLYTREK may cause vision problems. Your healthcare provider may stop ROZLYTREK and refer you to an eye specialist if you develop severe vision problems during treatment with ROZLYTREK. Tell your healthcare provider right away if you have any loss of vision or any change in vision, including:
 - double vision
 - blurry vision
 - new or increased floaters
 - seeing flashes of light
 - light hurting your eyes

Your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop ROZLYTREK if you develop certain side effects during treatment with ROZLYTREK.

What is ROZLYTREK?

ROZLYTREK is a prescription medicine used to treat:

- Adults with non-small cell lung cancer (NSCLC) that has spread to other parts of the body and is caused by an abnormal *ROS1* gene.
- Adults and children 1 month of age and older with solid tumors (cancer) that:
 - are caused by certain abnormal *NTRK* genes, **and**
 - have spread or if surgery to remove their cancer is likely to cause severe complications, **and**
 - there is no satisfactory alternative treatment option or the cancer grew or spread on other treatment.

It is not known if ROZLYTREK is safe and effective in children with *ROS1* NSCLC or in children under 1 month of age with *NTRK* solid tumors.

Before taking ROZLYTREK, tell your healthcare provider about all your medical conditions, including if you:

- have liver or kidney problems
- have any heart problems, including a condition called long QT syndrome
- have nervous system (neurological) problems
- have or have had eye or vision problems
- are pregnant or plan to become pregnant. ROZLYTREK can cause harm to your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with ROZLYTREK.

Females who can become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with ROZLYTREK.
- Use effective birth control (contraception) during treatment with ROZLYTREK and for at least 5 weeks after the last dose.

Males with female partners that can become pregnant:

- Use effective birth control (contraception) during treatment with ROZLYTREK and for 3 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if ROZLYTREK passes into your breast milk. Do not breastfeed during treatment with ROZLYTREK and for 7 days (1 week) after the last dose of ROZLYTREK. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements.

Taking ROZLYTREK with certain other medicines may affect the amount of ROZLYTREK or other medicine in your blood and may cause side effects or affect the way that ROZLYTREK or the other medicine work. Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ROZLYTREK?

- Take ROZLYTREK exactly as your healthcare provider tells you. Do not change your dose or stop taking ROZLYTREK unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with ROZLYTREK if you develop certain side effects.
- Take ROZLYTREK 1 time each day with or without food.
- Your healthcare provider will either prescribe:
 - ROZLYTREK capsules to be swallowed whole or prepared and taken or given as a suspension **or**
 - ROZLYTREK oral pellets to be sprinkled on 1 or more spoonfuls of soft food before taking.
- If you miss a dose of ROZLYTREK, take it as soon as you remember. If your next dose is due within 12 hours, skip the missed dose and take your next dose at your regular time.
- If you vomit right after taking a dose of ROZLYTREK, you may take the dose again.

See the detailed Instructions for Use for information on how to give or take a dose of ROZLYTREK capsules or oral pellets.

If you are taking whole ROZLYTREK capsules:

- Swallow whole capsules with drinking water, as directed by your healthcare provider.
- Do not crush or chew the capsule.

If you are taking ROZLYTREK capsules prepared as a suspension:

- Carefully open the prescribed number of capsules and pour the contents into room temperature drinking water or milk. Your healthcare provider will tell you how much water or milk to use, how much suspension to take or give, and provide you with a measuring device like an oral syringe or measuring cup.
- Let the suspension sit for 15 minutes before taking.
- You may need to take less suspension than you prepared depending on your prescribed dose.
- Drink water after taking the suspension to make sure you have swallowed all the medicine.
- If you do not take the suspension right away, you can store it for up to 2 hours at room temperature below 86°F (30°C). Throw away (discard) the unused suspension if it is not used within 2 hours of preparation.

- If you cannot swallow and have a gastric or nasogastric tube, the suspension can be given through the feeding tube.

If you are taking ROZLYTREK oral pellets:

- Sprinkle the prescribed number of packets of pellets on 1 or more spoonfuls of a soft food like 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 prescribed dose to make sure you have swallowed all the medicine.
- Use the whole packet of pellets. **Do not** use part of the packet to try to prepare a dose.
- **Do not** use the pellets to make a suspension.
- **Do not** give the pellets through a gastric or nasogastric tube because the pellets may clog the feeding tube.

What should I avoid while taking ROZLYTREK?

- You should not drink grapefruit juice or eat grapefruit during your treatment with ROZLYTREK. It may increase the amount of entrectinib in your blood to a harmful level and increase your chance of getting side effects.
- Do not drive or operate heavy machinery until you know how ROZLYTREK affects you. If you experience dizziness, fainting, tiredness, blurred vision, memory loss, changes in mental status, confusion, or hallucinations, do not drive or operate heavy machines until your symptoms resolve.

What are the possible side effects of ROZLYTREK?

ROZLYTREK may cause serious side effects, including:

- See “**What is the most important information I should know about ROZLYTREK?**”

The most common side effects of ROZLYTREK include:

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|-------------------|-------------------------------------|------------------|
| • tiredness | • nausea | • weight gain |
| • constipation | • abnormal touch sensation | • cough |
| • change in taste | • shortness of breath | • vomiting |
| • swelling | • muscle pain | • fever |
| • dizziness | • confusion, mental status changes, | • joint pain |
| • diarrhea | memory problems, and hallucinations | • vision changes |

These are not all the possible side effects of ROZLYTREK.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ROZLYTREK?

ROZLYTREK capsules

- Store ROZLYTREK at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ROZLYTREK capsules in the original container and keep the bottle tightly closed to protect from moisture.

ROZLYTREK oral pellets

- Store ROZLYTREK oral pellets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ROZLYTREK oral pellets in the original container to protect from moisture.

Keep ROZLYTREK and all medicines out of the reach of children.

General information about the safe and effective use of ROZLYTREK.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ROZLYTREK for a condition for which it was not prescribed. Do not give ROZLYTREK to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ROZLYTREK that is written for health professionals.

What are the ingredients in ROZLYTREK?

Active ingredient: entrectinib

Inactive ingredients:

Capsules: tartaric acid, lactose anhydrous, hypromellose, croscopovidone, microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate.

- Yellow opaque capsule shell: hypromellose, titanium dioxide, and yellow iron oxide
- Orange opaque capsule shell: hypromellose, titanium dioxide, and FD&C Yellow No. 6
- Printing ink: shellac, propylene glycol, strong ammonia solution, and FD&C Blue No. 2 aluminum lake

Pellets: tartaric acid, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, sodium stearyl fumarate, mannitol, and magnesium stearate

- **Film-coating: polyvinyl alcohol (partially hydrolyzed), titanium dioxide, polyethylene glycol 3350, talc, yellow iron oxide, red iron oxide, and ferrosferric oxide**

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For more information, go to www.ROZLYTREK.com or call 1-877-436-3683.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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