

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

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. Tell your healthcare provider right away if you have any of the following signs and symptoms of congestive heart failure:
 - persistent coughing or wheezing
 - increasing shortness of breath
 - trouble breathing when lying down
 - tiredness, weakness, or fatigue
 - sudden weight gain
 - 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, 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 have 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 symptoms of liver problems including: loss of appetite, nausea or vomiting, or pain on the upper right side of your stomach area. Your healthcare provider may temporarily stop treatment, decrease your dose, or permanently stop ROZLYTREK if you develop liver problems with ROZLYTREK.
- **Increased uric acid level in your blood (hyperuricemia).** ROZLYTREK may cause an excess of uric acid in your blood. Your healthcare provider may 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.
- **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
 - seeing flashes of light
 - blurry vision
 - light hurting your eyes
 - new or increased floaters

See “What are the possible side effects of ROZLYTREK?” for more information about side effects.

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 12 years 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 for use in children less than 12 years of age.

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 harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with ROZLYTREK or think you may be pregnant.

- If you are able to become pregnant, your healthcare provider will do a pregnancy test before you start treatment with ROZLYTREK.
- **Females** who are able to become pregnant should use effective birth control during treatment with ROZLYTREK and for at least 5 weeks after the final dose.
- **Males** who have female partners that are able to become pregnant should use effective birth control during treatment with ROZLYTREK and for 3 months after the final 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 after the final 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.

Certain other medicines may affect how ROZLYTREK works causing side effects. 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 to take it. 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 side effects.
- Take ROZLYTREK 1 time each day with or without food.
- Swallow whole ROZLYTREK capsules. Do not open, crush, chew or dissolve the capsule contents.
- 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.

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

These are not all the possible side effects of ROZLYTREK. For more information, ask your healthcare provider or pharmacist.

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?

- Store ROZLYTREK below 86°F (30°C).
- Store ROZLYTREK capsules in the original container and keep the bottle tightly closed in order 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 healthcare provider or pharmacist for information about ROZLYTREK that is written for health professionals.

What are the ingredients in ROZLYTREK?

Active ingredient: entrectinib

Inactive ingredients: tartaric acid, lactose anhydrous, hypromellose, crospovidone, microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate. Yellow opaque capsule shell contains: hypromellose, titanium dioxide, and yellow iron oxide. Orange opaque capsule shell contains: hypromellose, titanium dioxide, and FD&C Yellow No. 6. Printing ink contains: shellac, propylene glycol, strong ammonia solution, and FD&C Blue No. 2 aluminum lake.

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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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