Entrectinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for non-small cell lung cancer (NSCLC) and solid tumors that have a certain type of abnormal neurotrophic receptor tyrosine kinase (NTRK) gene.
- It may also be used for other reasons.
- Your care team may perform a test for a specific type of abnormal ROS1 gene to make sure entrectinib is right for you.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Entrectinib (en-TREK-tih-nib): Rozlytrek (roz-LY-trek)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	• Capsule(s) taken by mouth. • Capsule(s) for oral suspension taken by mouth or given through a feeding tube. • Oral pellets taken by mouth after mixing with soft food.

Treatment Administration and Schedule

Your entrectinib dosing instructions:

_____

_____

_____

- Entrectinib comes in 2 capsule strengths: 100 mg and 200 mg; and 1 oral pellet strength: 50 mg.
- Your dose might differ, but entrectinib is typically taken as three 200 mg capsules (600 mg total dose) by mouth once daily.
- Take entrectinib 1 time each day, around the same time each day, with or without food.
- Your care team will either prescribe:
  - Entrectinib capsules to be swallowed whole or prepared and taken or given as a suspension or
  - Entrectinib oral pellets to be sprinkled on 1 or more spoonfuls of soft food before taking.

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Treatment Administration and Schedule (Continued)

- Do not change your dose or stop taking entrectinib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking entrectinib if you develop certain side effects.
- 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 and take your next dose at your regular time.
- If you vomit right after taking a dose of entrectinib, you may take the dose again.
- If you take too much entrectinib, call your care team or go to the nearest hospital emergency room right away.

☐ **Entrectinib Capsules**

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

☐ **Entrectinib Capsules for Suspension**

- Carefully open the prescribed number of capsules and pour the contents into room temperature drinking water or milk. Your care team 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 (NG) tube, the suspension can be given through the feeding tube.

Storage and Handling of Entrectinib Capsules

- Store entrectinib at room temperature between 68°F and 77°F (20°C and 25°C).
- Store entrectinib capsules in the original container and keep the bottle tightly closed to protect from moisture.
- Keep entrectinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused entrectinib.

☐ **Entrectinib 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 (G) or nasogastric (NG) tube because the pellets may clog the feeding tube.

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Storage and Handling of Entrectinib Oral Pellets

- Store entrectinib at room temperature between 68°F and 77°F (20°C and 25°C).
- Store entrectinib oral pellets in the original container to protect from moisture.
- Keep entrectinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused entrectinib.

Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss an appointment, call your care team as soon as possible to reschedule it.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
Supportive care used to treat or prevent side effects	

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Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: Red blood cells carry oxygen throughout your body. Low levels can make you feel tired, weak, dizzy, or short of breath. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache
Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. Talk to your care team if you have: • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness

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Your Body May Hold Too Much Fluid (Fluid Retention) Leading to Swelling (Edema)	Description: Fluid retention (edema) is swelling caused by excess fluid in body tissues, often seen in the legs, ankles, feet, hands, or abdomen. It can cause tightness, weight gain, and discomfort. Recommendations: • Weigh yourself daily and keep a record to notice sudden weight gain. • Elevate swollen legs when sitting and avoid standing for long periods. • Wear compression stockings if your care team recommends them. • Remove rings if your fingers begin to swell. • Limit salt (sodium) intake and follow any fluid restrictions your care team gives. • Stay active and do gentle movement to improve circulation. Talk to your care team if you have: • Swelling that suddenly worsens or spreads to other areas • Pain, redness, or warmth in the affected area • Shortness of breath or difficulty breathing • Persistent swelling that does not improve with home management • Unexpected weight gain Note: Your care team may ask you to contact them if your weight increases by a certain amount over a certain time period.
Taste Changes	Description: Your sense of taste may change. Foods you used to like may not taste good. Some foods may taste strange or like metal. Recommendations: • Choose foods that look and smell good to you. • If food tastes like metal, try using plastic forks and spoons. • Use herbs, spices, or a little juice to add flavor. • Suck on mints or chew gum to freshen your mouth. • Brush your teeth with a soft toothbrush before and after eating. • Do not smoke. Talk to your care team if you have: • Trouble eating • Weight loss
Nausea and Vomiting	Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit. Recommendations: • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods. • Your care team may prescribe medicine for these symptoms. Talk to your care team if you have: • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood in your vomit or vomit that looks like coffee grounds • Severe stomach pain that does not go away after vomiting

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Liver Problems	Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment. Talk to your care team if you have: • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal
Constipation	Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain. Recommendations: • Track how often you have bowel movements each day. • Drink 8 to 10 glasses of fluids daily, unless your care team says otherwise. • Stay active and exercise regularly. • Eat more high-fiber foods (such as raw fruits, vegetables, and whole grains) unless advised otherwise. • Your care team may recommend laxatives such as polyethylene glycol (MiraLAX) or senna. Talk to your care team if you have: • Constipation lasting 3 or more days • No bowel movement 48 hours after using a laxative
Diarrhea	Description: Diarrhea means having bowel movements more often than usual. Your stools may also be loose or watery. If you have diarrhea: • Keep track of how often you have diarrhea. • Drink 8 to 10 glasses of water or fluids each day. Do this unless your care team tells you otherwise. • Eat small meals with low-fiber foods. Try bananas, applesauce, potatoes, chicken, rice, or toast. • Avoid high-fiber foods. These include raw vegetables, fruit, and whole grains. • Avoid foods that may cause gas. These include broccoli and beans. • Avoid milk, yogurt, and other dairy foods. • Avoid spicy, fried, or greasy foods. • Your care team may recommend medicine for diarrhea. One example is loperamide (Imodium). Talk to your care team if you have: • An increase of 4 or more bowel movements than usual in one day • Dizziness or lightheadedness while you have diarrhea • Signs of dehydration, such as feeling very thirsty, dizzy, or having dark urine • Blood in your stool

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Kidney Problems	Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment. Recommendations: • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. Talk to your care team if you have: • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
Cough and Shortness of Breath	Description: During treatment, you may start coughing more than usual. You may also feel like you can't catch your breath or that breathing is harder. Recommendations: • Drink 8 to 10 glasses of water each day to help with mucus. • Avoid and stop smoking. • Use a humidifier to make the air moist. • Try slow, deep breathing. • Use extra pillows to keep your head up when you sleep. Talk to your care team if you have: • Trouble breathing • Chest pain or tightness • Cough
Burning or Painful Skin Sensations (Dysesthesia)	Description: Dysesthesia is an uncomfortable or unpleasant feeling on your skin. It may feel like burning, tingling, prickling, electric shocks, or pain even when touched lightly or without a clear cause. Recommendations: • Keep a daily log of pain and sensations, noting triggers and what helps or makes it worse. • Protect sensitive areas from extreme heat, cold, or rough surfaces. • Use gentle skin care and avoid scratching or rubbing painful areas. • Your care team may recommend or prescribe medicines, topical treatments, physical therapy, or supplements to help with symptoms. Talk to your care team if you have: • New or worsening burning, tingling, or painful skin sensations • Pain from light touch or clothing • Symptoms that interfere with walking, using your hands, sleeping, or daily activities • Severe or persistent pain that does not improve

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Changes in Electrolytes and Other Laboratory Results	Description: Treatment may cause high levels of sodium, magnesium, and uric acid, and low levels of calcium and phosphate in your blood. Your care team will perform blood tests to check for these changes and will treat you if needed. Talk to your care team if you have: • Extreme thirst • Muscle twitching, spasms, cramps, or bone pain • Seizures • Trouble thinking, speaking, or walking • Severe headache • New or worsening muscle weakness or loss of reflexes • Trouble breathing or slow, shallow breathing, or shortness of breath • Marked drowsiness, confusion, slurred speech, or severe dizziness • Very low blood pressure or a feeling of near-fainting • Irregular, fast, slow, or pounding heartbeat • Sudden, severe joint pain, redness, or swelling (possible gout) • Severe flank or abdominal pain, blood in the urine, or difficulty urinating (possible kidney stone) • Little or no urine output or sudden weight gain from fluid • Fever, chills, or signs of infection • New or worsening kidney test results • Tingling or numbness around the mouth, hands, or feet • Sudden weight gain • Swelling of your arms, hands, legs, or ankles • Severe fatigue or inability to perform daily activities

Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Changes in the Electrical Activity of Your Heart Called QT Prolongation	QT prolongation can cause irregular heartbeats that can be life-threatening. • Feel faint, lightheaded, dizzy • Fast or irregular heartbeat
Heart Problems	• Swelling of your stomach area (abdomen), legs, hands, feet, or ankles • Shortness of breath • Nausea or vomiting • New or worsening chest discomfort, including pain or pressure • Weight gain • Pain or discomfort in your arms, back, neck, or jaw • Protruding neck veins • Breaking out in a cold sweat • Feeling lightheaded or dizzy
Brain or Eye Problems	• Headaches • Dizziness or lightheadedness • Confusion or difficulty concentrating • Memory loss • Weakness or numbness in parts of the body • Changes in mood or behavior • Seizure • Coordination or balance issues • Blurred or double vision • Sudden vision loss, eye pain or discomfort • Redness or swelling in the eyes • Sensitivity to light • Visual disturbances, such as flashes of light or floaters

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Bone Fracture	• Sharp pain that worsens with movement • Swelling or bruising around the broken bone	• Difficulty moving or bearing weight on the injured area • Limb that looks crooked, bent, or shorter than the other side

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment may **harm an unborn baby**.
    - If you are able to become pregnant:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment and for 5 weeks after your last dose of entrectinib.
        - If you think you might be pregnant or if you become pregnant, tell your care team right away.
    - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for 3 months after your last dose of entrectinib.
- **Do not breastfeed** during treatment and for 1 week after your last dose of entrectinib.

Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **You should not drink grapefruit juice or eat grapefruit during treatment with entrectinib**. Grapefruit may increase the amount of entrectinib in your blood.
- **Entrectinib can make you feel dizzy**. Do not drive or operate machinery until you know how entrectinib affects you.
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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Updated Date: October 30, 2026

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