

**INSTRUCTIONS FOR USE**  
**ROZLYTREK® [roz lye trek]**  
(entrectinib)  
oral pellets

This Instructions for Use contains information on how to prepare and take or give ROZLYTREK oral pellets.

**Before Starting**

**Read this Instructions for Use** before giving ROZLYTREK oral pellets for the first time and each time you get a refill. There may be new information.

Sprinkle ROZLYTREK oral pellets on 1 or more spoonfuls of a soft food before taking or giving.

**Do not** use ROZLYTREK oral pellets to prepare a suspension.

**Do not** give or take ROZLYTREK oral pellets through a gastrostomy tube (G Tube) or nasogastric tube (NG Tube) because the pellets may clog the feeding tube.

**Important Information You Need to Know Before Preparing and Taking or Giving ROZLYTREK Oral Pellets**

- Your healthcare provider should show you how to properly prepare and take or give a daily dose of ROZLYTREK oral pellets. Always take or give ROZLYTREK oral pellets exactly as your healthcare provider tells you.
- **Do not** take ROZLYTREK oral pellets or give it to someone else until you have been shown how to properly prepare and take or give ROZLYTREK.
- Wash your hands before and after preparing, taking, or giving ROZLYTREK.
- Check the expiration date and check the product for damage before use. **Do not** use if expired or damaged.

**Dosing ROZLYTREK oral pellets**

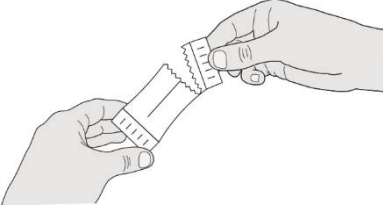
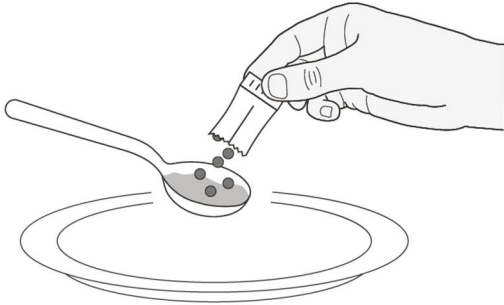
- Your healthcare provider will decide the right dose of ROZLYTREK for you or your child.
- ROZLYTREK oral pellets come in a carton with 42 packets. Each packet contains 50 mg of ROZLYTREK.
- Use the whole packet of pellets. **Do not** use part of the packet to try to prepare a dose.
- Sprinkle the prescribed number of packets on 1 or more spoonfuls of soft food and take or give within 20 minutes of sprinkling the pellets on the soft food.
- **Do not** crush or chew the pellets to avoid a bitter taste.

**Supplies needed to prepare and take or give ROZLYTREK oral pellets:**

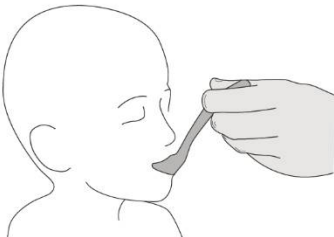



- the number of packets needed for your prescribed dose
- a clean spoon
- a paper towel or clean plate
- soft food like applesauce, yogurt, or pudding

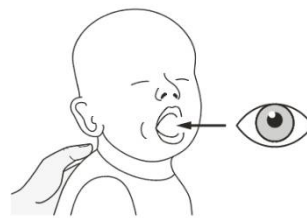
## Preparing to take or give ROZLYTREK oral pellets

<p><b>Step 1.</b> Wash your hands.</p>	
<p><b>Step 2.</b> Get a soft food like applesauce, yogurt, or pudding to use to take or give ROZLYTREK oral pellets.</p>	
<p><b>Step 3.</b> Count the number of packets you will need to give the prescribed dose.</p> <ul style="list-style-type: none"><li>• Tap the packets to make sure that the pellets are on one side of the packet.</li><li>• Hold the side of the packet where the pellets are tapped and open the other side of the packet with your other hand or with scissors (<b>Figure A</b>).</li></ul> <p><b>Note:</b> Make sure that you do not cut the pellets with scissors.</p>	 <p><b>Figure A</b></p>
<p><b>Step 4.</b> Get a spoonful of the soft food and hold the spoonful above a paper towel or clean plate.</p> <ul style="list-style-type: none"><li>• Sprinkle the prescribed number of packets on the spoonful of soft food (<b>Figure B</b>).</li><li>• Tap the packets to make sure all pellets are sprinkled on the food.</li></ul> <p><b>Note:</b> You may need to use more than 1 spoonful of soft food to give the prescribed dose. If you need to use another spoonful, finish step 5 and then repeat steps 4 and 5.</p>	 <p><b>Figure B</b></p>

## Giving ROZLYTREK oral pellets

<p><b>Step 5.</b> Take or give the spoonful of food with the pellets sprinkled on it right away (<b>Figure C</b>).</p> <p>Take or give the spoonful of soft food <b>within 20 minutes</b> after sprinkling the pellets on it if you cannot take or give it right way.</p> <p><b>Note:</b> If you leave the pellets in the soft food for too long it may dissolve the coating and cause a bitter taste. <b>Do not</b> crush or chew the pellets because this may also cause a bitter taste.</p> <p><b>Throw away</b> the soft food with the pellets sprinkled on it <b>if you do not take it within 20 minutes</b> and prepare a new dose (start at Step 1).</p> <p>If you need more than 1 spoonful of soft food to take or give the prescribed dose, repeat steps 4 and 5.</p>	 <p><b>Figure C</b></p>
<p><b>Step 6.</b> Give sips of water after taking or giving the prescribed dose to make sure all the pellets are swallowed. (<b>Figure D</b>).</p> <p>A meal or drink can be given after taking the ROZLYTREK dose to help with the taste.</p>	 <p><b>Figure D</b></p>

**Step 7.** Check the mouth to make sure that all of the pellets were swallowed (**Figure E**). If not all pellets are swallowed, give more sips of water.



**Figure E**

#### **Cleaning up and disposing of ROZLYTREK oral pellets**

- Wash your hands and all the items used to give ROZLYTREK.
- Throw away (discard of) the disposable items in your household trash.

#### **Storing 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.

Distributed by:

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For more information, go to [www.ROZLYTREK.com](http://www.ROZLYTREK.com) or call 1-877-436-3683.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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