

**INSTRUCTIONS FOR USE**  
**ROZLYTREK® [roz lye trek]**  
(entrectinib)  
capsules, for oral use

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

**Before Starting**

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

ROZLYTREK capsules can be swallowed whole or prepared as a suspension and taken or given by mouth or through a nasogastric tube (NG tube) or gastrostomy tube (G tube) feeding tube.

**Important Information You Need to Know Before Taking or Giving ROZLYTREK Capsules**

- Your healthcare provider or pharmacist should show you how to correctly prepare and take or give a dose of ROZLYTREK capsules. Always take or give ROZLYTREK capsules exactly as your healthcare provider tells you.
- **Do not** take or give ROZLYTREK 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 of ROZLYTREK capsules to be swallowed whole**

- Your healthcare provider will decide the right dose of ROZLYTREK for you or your child.
- Your healthcare provider will tell you what your daily dose of ROZLYTREK is.
- Swallow ROZLYTREK capsules whole, with or without food.
- Swallow whole capsules with drinking water, as directed by your healthcare provider.
- **Do not** crush or chew the capsules.

**Dosing of ROZLYTREK capsules prepared as a suspension to be taken by mouth or through a feeding tube**

If you or your child cannot swallow capsules whole, ROZLYTREK capsules can be prepared as a suspension and taken or given by mouth or through a feeding tube. For doses of 3 mL or higher, a NG or G feeding tube size 8 French or larger should be used.

Your healthcare provider or pharmacist will show you how to prepare and take or give a dose of ROZLYTREK capsules prepared as a suspension.

**Table 1** shows the prescribed dose, the number and strength of capsules needed, the amount of water or milk needed to mix the capsules, and the amount of suspension needed to give for the prescribed dose.

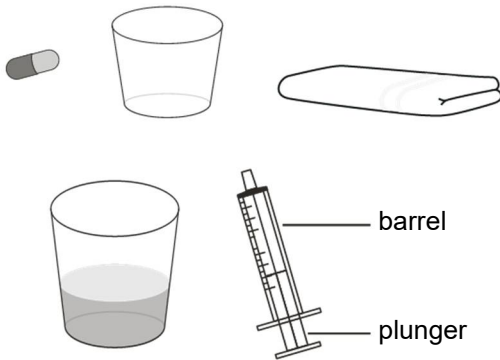
**Your healthcare provider will tell you** the number of capsules to use, the amount of liquid needed to mix the capsules, and the amount of suspension (mL) to take or give to get the correct dose of ROZLYTREK.

**You may need to measure a smaller amount of suspension than you prepared to take or give the correct prescribed dose of ROZLYTREK.**

<b>Prescribed dose of ROZLYTREK to be given</b>	<b>Number of 100 mg or 200 mg capsules needed</b>	<b>Amount of water or milk needed to mix the capsules</b>	<b>Amount of suspension to take or give</b>
20 mg	One 100 mg	5 mL	1 mL
30 mg	One 100 mg	5 mL	1.5 mL
40 mg	One 100 mg	5 mL	2 mL
50 mg	One 100 mg	5 mL	2.5 mL
60 mg	One 100 mg	5 mL	3 mL
70 mg	One 100 mg	5 mL	3.5 mL
80 mg	One 100 mg	5 mL	4 mL
90 mg	One 100 mg	5 mL	4.5 mL
100 mg	One 100 mg	5 mL	5 mL
110 mg	One 200 mg	10 mL	5.5 mL
120 mg	One 200 mg	10 mL	6 mL
130 mg	One 200 mg	10 mL	6.5 mL
140 mg	One 200 mg	10 mL	7 mL
150 mg	One 200 mg	10 mL	7.5 mL
200 mg	One 200 mg	10 mL	10 mL
300 mg	Three 100 mg	15 mL	15 mL
400 mg	Two 200 mg	20 mL	20 mL
600 mg	Three 200 mg	30 mL	30 mL

**Supplies needed to prepare and take or give ROZLYTREK as a suspension:**

- the number of capsules needed for your prescribed dose
- a clean empty cup
- a paper towel
- a cup of room temperature drinking water or milk
- an oral syringe (provided by your healthcare provider or pharmacist)



## Preparing ROZLYTREK capsules as a suspension

**Step 1.** Wash your hands.

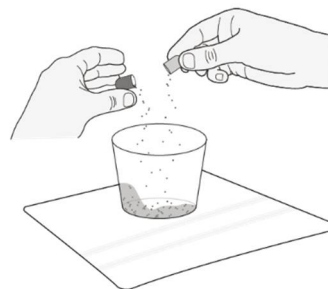
**Step 2.** Count the number of capsules you will need to give the prescribed dose.

**Step 3.** Place a clean empty cup on a paper towel.

**Step 4.** Tap the capsules to loosen the contents inside (medicine).

**Step 5.** While holding each capsule above the clean cup, open the capsule by gently pressing in on the capsule and twisting both sides apart.

Pour the medicine into the clean cup (**Figure A**).

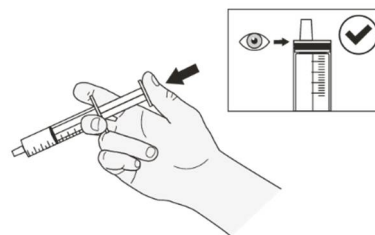


**Figure A**

**Step 6.** Tap both sides of the capsule shell and check to make sure all the medicine has gone into the cup.

- If the medicine is spilled outside of the cup, go to Step D1 for clean-up instructions, then start over at Step 1.

**Step 7.** Push the syringe plunger all the way down to remove any air in the oral syringe (**Figure B**).



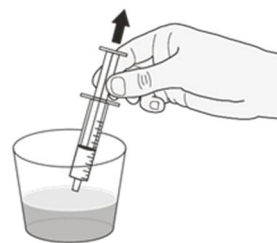
**Figure B**

**Step 8.** Place the syringe tip into the room temperature cup of drinking water or milk.

Measure the proper amount of liquid (mL) by pulling up on the syringe plunger to draw the liquid into the syringe (**Figure C**).

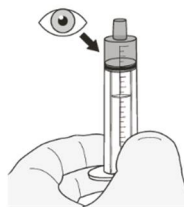
**Your healthcare provider will tell you how much liquid to use.**

**Do not** use any other type of liquid.



**Figure C**

**Step 9.** Check that the correct amount of liquid (mL) is in the syringe (**Figure D**).



**Figure D**

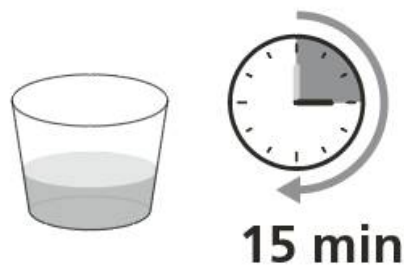
**Step 10.** Add the liquid to the cup that contains the medicine by holding the barrel of the syringe and pushing the syringe plunger all the way down (**Figure E**).



**Figure E**

**Step 11.** Let the mixture sit for 15 minutes (**Figure F**).

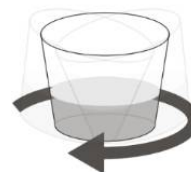
**Note:** It is important to do this to get an even mixture, otherwise you may not get the correct dose.



**Figure F**

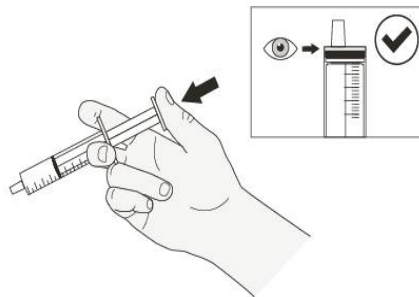
**Step 12.** Swirl the cup several times to evenly mix the medicine in the liquid (**Figure G**).

**Note:** The medicine does not dissolve in the liquid and the suspension will be cloudy if you have used water.



**Figure G**

**Step 13.** Push the syringe plunger all the way down to remove any air in the syringe (**Figure H**).



**Figure H**

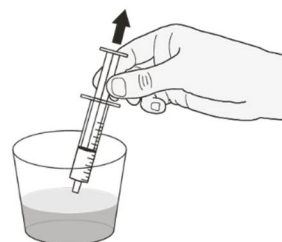
**Step 14.** Swirl the cup of medicine again before placing the syringe in the cup (**Figure I**).



**Figure I**

**Step 15.** Place the syringe tip right away into the cup and slowly pull up the plunger to draw up the correct amount (mL) of suspension (**Figure J**).

**Do not** wait to draw up the suspension. If it sits for too long, the medicine may settle to the bottom, and you may not get the correct dose.



**Figure J**

**Step 16.** Check that the correct amount of suspension (mL) is in the syringe (**Figure K**).



**Figure K**

**Step 17.** With the tip of the syringe pointing up, check that:

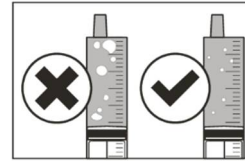
- you have withdrawn the correct amount (mL)
- there are no large bubbles (**Figure L**)

**Note:** If you have not withdrawn the correct amount (mL), or if there are large bubbles inside:

- put the syringe into the cup again
- push the suspension back into the cup
- then draw up the suspension again (start at Step 12).

Give ROZLYTREK right away after it is drawn up into the syringe.

**NOTE:** Throw away the suspension if you do not take or give it **within 2 hours of preparing** the suspension and start over at step 1.



**Figure L**

### Giving ROZLYTREK capsules prepared as a suspension by mouth

**Step A1.** Sit your child upright when you give a dose of ROZLYTREK by mouth (**Figure M**).

Place the oral syringe into the mouth with the tip along either cheek.

Slowly push the plunger all the way down.

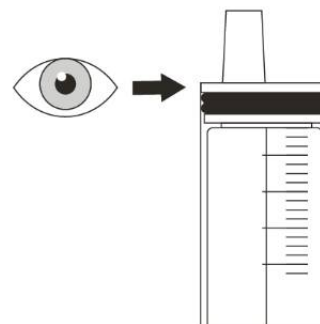
Giving ROZLYTREK too fast may cause choking.



**Figure M**

**Step A2.** Check that there is no suspension left in the oral syringe (**Figure N**).

If suspension remains in the oral syringe, repeat step A1.



**Figure N**

**Step A3.** Give sips of water right after taking or giving the prescribed dose of ROZLYTREK (**Figure O**).

You can breastfeed or give your child milk if they still taste the medicine after you give the dose.

**Go to Step D1 for clean-up instructions.**



**Figure O**

### Giving ROZLYTREK capsules prepared as a suspension through a gastrostomy tube (G tube)

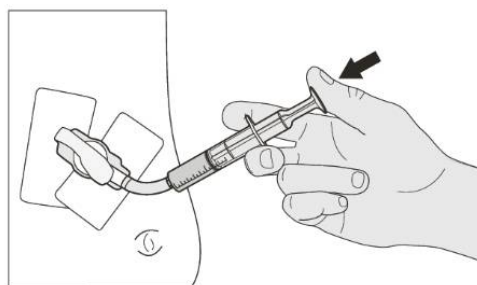
To take or give ROZLYTREK through a G tube review the manufacturer's instructions and consult your healthcare provider. Make sure that the tube is at least 8 French or larger to prevent clogging of the tube if your dose (amount of suspension) is 3 mL or higher.

To take or give ROZLYTREK doses of 3 mL or higher, split the dose in half and give it in 2 parts. Flush the tube with the same amount of water or milk after giving each part.

To take or give ROZLYTREK doses of 30 mL, split the dose into at least three 10 mL parts. Flush the tube with the same amount of water or milk after giving each part.

#### Step B1

Place the oral syringe tip into the G tube. Slowly push the plunger all the way down to give ROZLYTREK (**Figure P**).

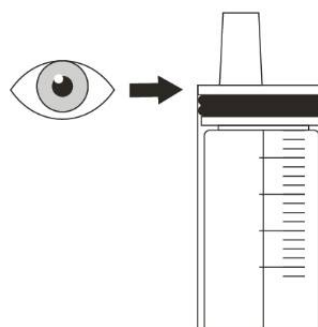


**Figure P**

#### Step B2

Check that there is no suspension left in the oral syringe (**Figure Q**).

If suspension remains in the oral syringe, repeat step B1.



**Figure Q**

**Step B3**

Flush the G tube with water or milk right after giving ROZLYTREK (Figure R).

If you need to split the amount of suspension to give it through the G tube, also split the amount of water or milk you use to flush the tube in the same way.

Ask your healthcare provider if you are not sure how much water or milk to use to flush the G tube.

Go to Step D1 for clean up instructions.

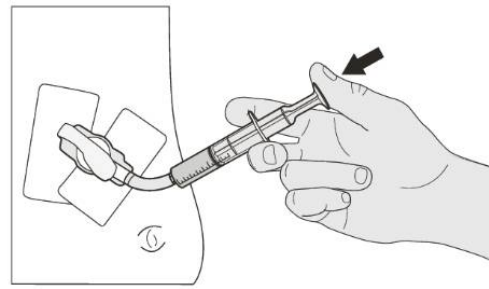


Figure R

**Giving ROZLYTREK capsules prepared as a suspension through a nasogastric tube (NG tube)**

If you are giving ROZLYTREK through an NG tube, review the manufacturer instructions and consult your healthcare provider. Make sure that the tube is at least 8 French or larger to prevent clogging of the tube if your dose (amount of suspension) is 3 mL or higher.

To take or give ROZLYTREK doses of 3 mL or higher, split the dose in half and give it in 2 parts. Flush the tube with the same amount of water or milk after giving each part.

To take or give ROZLYTREK doses of 30 mL, split the dose into at least three 10 mL parts. Flush the tube with the same amount of water or milk after giving each part.

**Step C1**

Place the syringe tip into the NG tube. Slowly press the plunger all the way down to give ROZLYTREK (Figure S).

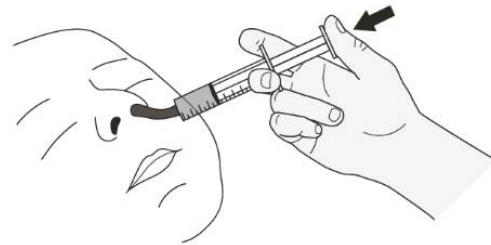


Figure S

**Step C2**

Check that there is no suspension left in the syringe (Figure T).

If suspension remains in the syringe, repeat step C1.

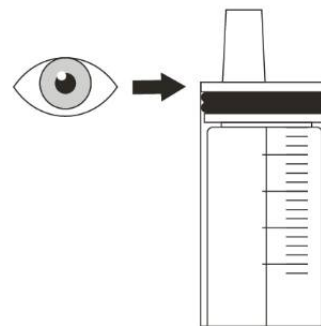


Figure T



**Step C3**

Flush the NG tube with water or milk right after giving ROZLYTREK (**Figure U**).

**If you need to split the amount of suspension to give it through the NG tube, also split the amount of water or milk you use to flush the tube in the same way.**

Ask your healthcare provider if you are not sure how much water or milk to use to flush the NG tube.

**Go to Step D1 for clean up instructions.**



**Figure U**

**Cleaning up and disposing of ROZLYTREK****Step D1**

- Wash your hands and all the items used to give ROZLYTREK.
- Remove the syringe plunger from the syringe barrel.
- Use only clean water to rinse the syringe parts and the cup used to prepare the suspension. Let all items dry before the next use.
- Put the syringe plunger back into the syringe barrel when dry.
- Throw away (discard of) the disposable items in your household trash.

**Storing ROZLYTREK**

- Store ROZLYTREK capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not store ROZLYTREK prepared as a suspension for more than 2 hours at room temperature below 86°F (30°C). Throw away any unused suspension if it is not used within 2 hours of preparation.
- Store ROZLYTREK capsules in the original container and keep the bottle tightly closed 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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