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Instructions For Use Everolimus (E-ver-OH-li-mus) Tablets for Oral Suspension

Read these Instructions for Use for everolimus tablets for oral suspension before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Important Information:

- **Take everolimus tablets for oral suspension as a suspension only.** Everolimus tablets for oral suspension is prepared as a suspension of undissolved medicine that is mixed with water, and then it is taken by mouth. Do not chew, crush, or swallow everolimus tablets for oral suspension whole.
- **Everolimus tablets for oral suspension can cause harm to an unborn baby.** When possible, the suspension should be prepared by an adult who is not pregnant or planning to become pregnant.
- Keep everolimus tablets for oral suspension and the prepared suspension out of the reach of children.
- Anyone who prepares suspensions of everolimus tablets for oral suspension for another person should wear gloves to avoid possible contact with the drug.
- Only use water with everolimus tablets for oral suspension to prepare the suspension. Do not prepare the suspension with juice or any other liquids.
- The suspension must be given right away. If you do not give the dose within 60 minutes after it has been prepared, throw away the dose and prepare a new dose of everolimus tablets for oral suspension.
- Before starting to prepare the suspension, collect all of the supplies that you will need to prepare and take the suspension. Do not use any of these supplies for purposes other than preparing and taking the everolimus tablets for oral suspension.

Supplies needed to prepare the suspension in an oral syringe:

- Blister card with everolimus tablets for oral suspension
- Scissors to open the blister card
- Disposable gloves (for one time use)
- 2 clean drinking glasses
- Approximately 30 mL of water
- 10 mL oral syringe (for one time use) (see Figure A)
- Paper towels

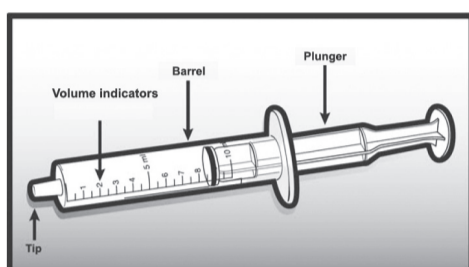


Figure A

Supplies needed to prepare the suspension in a small drinking glass:

- Blister card with everolimus tablets for oral suspension
- Scissors to open the blister card
- Disposable gloves (for one time use)
- 30 mL dose cup for measuring water (you can ask your pharmacist for this)
- 1 clean drinking glass (maximum size 100 mL)
- Water to prepare the suspension
- Spoon for stirring
- Paper towels

Preparing a dose of everolimus tablets for oral suspension using an oral syringe:

Step 1: Prepare a clean, flat work surface that is away from where you prepare and eat food. Place a clean paper towel on the work surface. Place the needed supplies on the paper towel.

Step 2: Wash and dry your hands well before preparing the medicine (see Figure B).



Figure B

Step 3: If preparing the everolimus tablets for oral suspension for another person, put on disposable gloves (see Figure C).



Figure C

Step 4: Take a 10 mL oral syringe and pull back on the plunger. Remove the plunger from the barrel of the syringe (see Figure D).

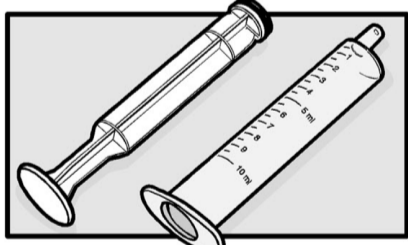


Figure D

Step 5: Use scissors to open the blister card along the dotted line (see Figure E) and remove the prescribed number of everolimus tablets for oral suspension from the blister card. Place them into the barrel of the oral syringe (see Figure F).

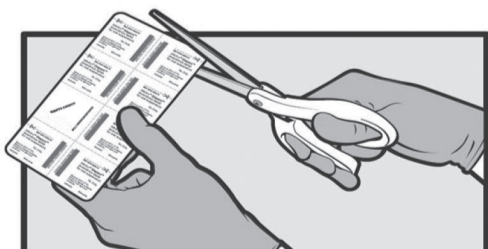


Figure E

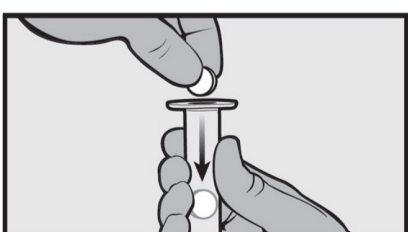


Figure F

Doses of up to 10 mg can be prepared with the oral syringe. **If your total prescribed dose is more than 10 mg, you will need to split the dose. Follow steps 4 through 17 for the first half of the dose. Then repeat steps 4 through 17 for the second half of the dose. Do not prepare a dose of more than 10 mg in one syringe.** Ask your pharmacist or healthcare provider if you are not sure what to do.

Step 6: Re-insert the plunger into the barrel of the oral syringe (see Figure G) and push the plunger in until it comes into contact with the everolimus tablets for oral suspension (see Figure H).

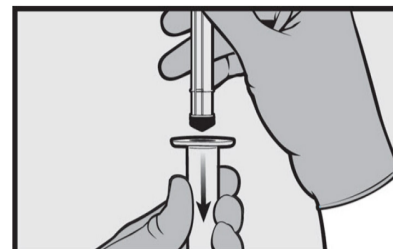


Figure G

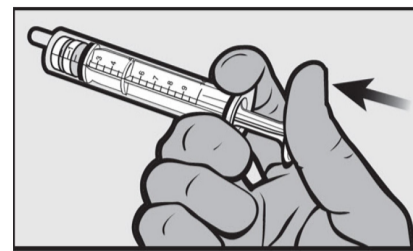


Figure H

Step 7: Fill a small drinking glass with about 30 mL of water. Insert the tip of the oral syringe into the water. Then slowly pull back on the plunger until the syringe is about half full of water and all the tablets are covered by water (see Figure I).



Figure I

Step 8: Hold the oral syringe with the tip pointing up. Pull back on the plunger to draw back about 4 mL of air (see Figure J).

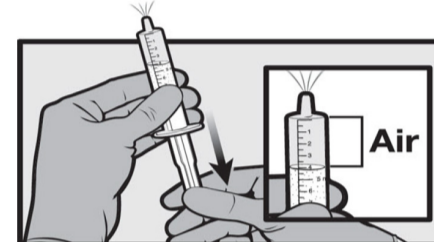


Figure J

Step 9: Place the filled oral syringe in the clean, empty glass with the tip pointing up. Wait **3 minutes** to allow everolimus tablets for oral suspension to break apart (see Figure K).

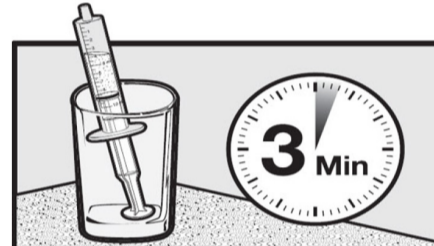


Figure K

Step 10: Slowly turn the oral syringe up and down five times just before giving the dose (see Figure L). **Do not shake** the syringe.

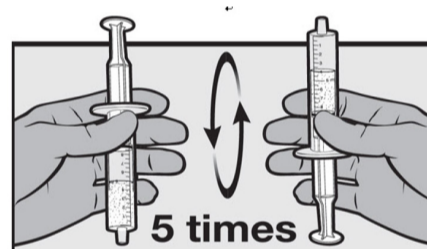


Figure L

Step 11: Hold the oral syringe in an upright position (with the tip up). Carefully remove most of the air by pushing up gently on the plunger (see Figure M).

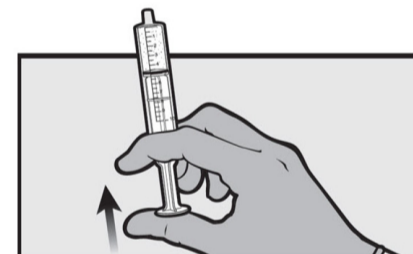


Figure M

Step 12: Give the full contents of the oral syringe slowly and gently into the mouth right away, within 60 minutes of preparing it (see Figure N). Carefully remove the syringe from the mouth. Continue with steps 13 through 17 to make sure that the entire dose of medicine is given.

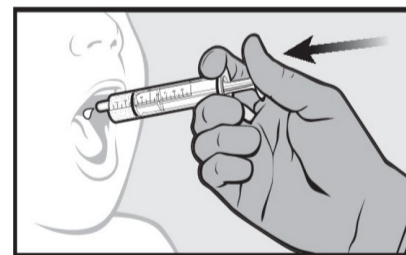


Figure N

Step 13: Insert the tip of the oral syringe into the drinking glass that is filled with water, and pull up about 5 mL of water by slowly pulling back on the plunger (see Figure O).

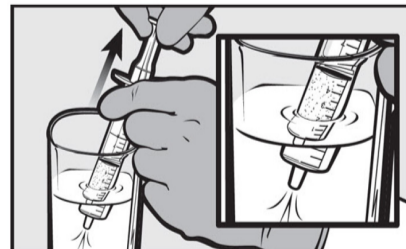


Figure O

Step 14: Hold the oral syringe with the tip pointing up and use the plunger to draw back about 4 mL of air (see Figure P).

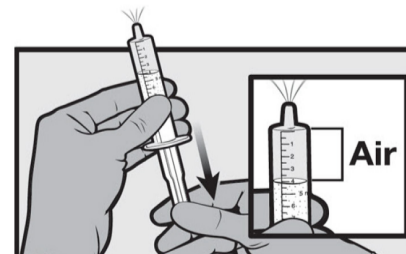


Figure P

Step 15: With the tip of the syringe still pointing up, swirl the contents by gently rotating the syringe in a circular motion (see Figure Q).

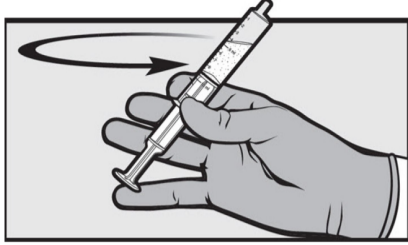


Figure Q

Step 16: Hold the oral syringe in an upright position (with the tip up). Carefully remove most of the air by pushing up gently on the plunger (see Figure R).

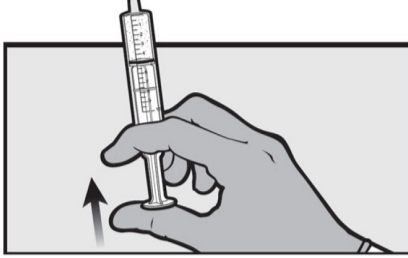


Figure R

Step 17: Give the full contents of the oral syringe slowly and gently into the mouth by pushing on the plunger (see Figure S). Carefully remove the syringe from the mouth.

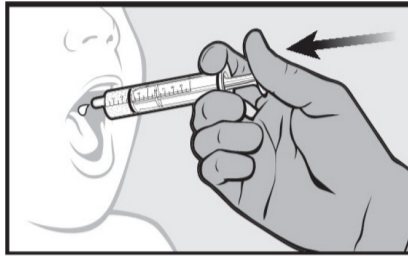


Figure S

If the total prescribed dose is more than 10 mg, repeat steps 4 through 17 to finish giving the dose.

Step 18: Throw away the oral syringe, paper towel, and used gloves in your household trash.

Step 19: Wash your hands.

Preparing a dose of everolimus tablets for oral suspension using a small drinking glass:

Step 1: Prepare a clean, flat work surface that is away from where you prepare and eat food. Place a clean paper towel on the work surface. Place the needed supplies on the paper towel.

Step 2: Wash and dry your hands before preparing the medicine (see Figure T).



Figure T

Step 3: If preparing the everolimus tablets for oral suspension for another person, put on disposable gloves (see Figure U).

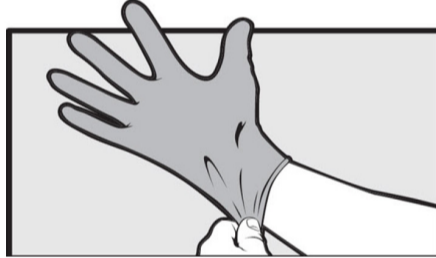


Figure U

Step 4: Add about 25 mL of water to the 30 mL dose cup. The amount of water added does not need to be exact (see Figure V).

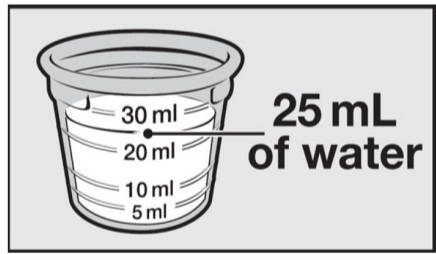


Figure V

Step 5: Pour the water from the dose cup into a small drinking glass (maximum size 100 mL) (see Figure W).



Figure W

Doses up to 10 mg can be prepared in the small drinking glass. **If your total prescribed dose is more than 10 mg, you will need to split the dose.**

Follow steps 4 through 10 for the first half of the dose. Then repeat steps 4 through 10 for the second half of the dose. Ask your pharmacist or healthcare provider if you are not sure what to do.

Step 6: Use scissors to open the blister card along the dotted line (see Figure X) and remove the prescribed number of everolimus tablets for oral suspension from the blister card.

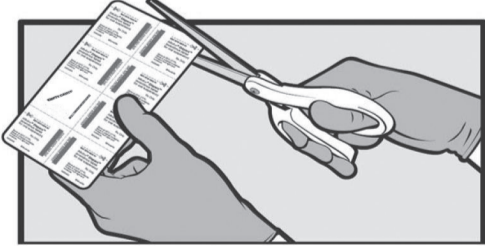


Figure X

Step 7: Add the prescribed number of everolimus tablets for oral suspension into the water (see Figure Y).

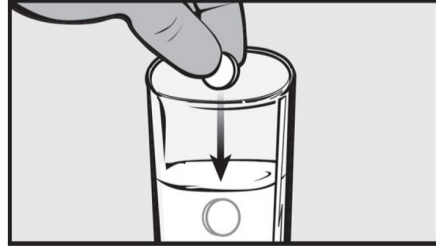


Figure Y

Step 8: Wait **3 minutes** to allow everolimus tablets for oral suspension to break apart (see Figure Z).

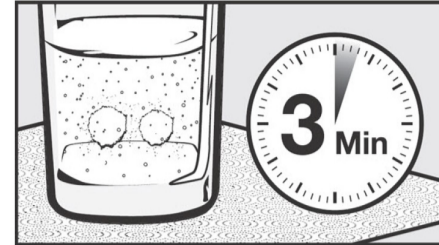


Figure Z

Step 9: Gently stir the contents of the glass with a spoon and place the spoon back on the paper towel (see Figure AA). Drink the full amount of the suspension right away, within 60 minutes of preparing it (see Figure BB).

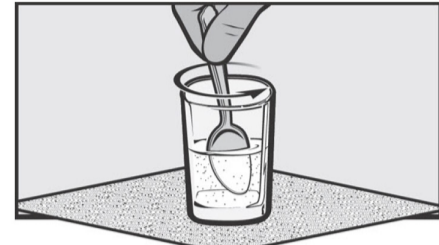


Figure AA

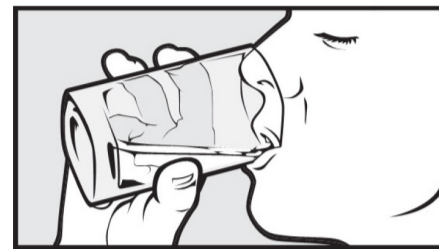


Figure BB

Step 10: Refill the glass with the same amount of water (about 25 mL). Stir the contents with the same spoon and place the spoon back on the paper towel (see Figure CC). Drink the full amount right away so that you take any remaining medicine (see Figure DD).

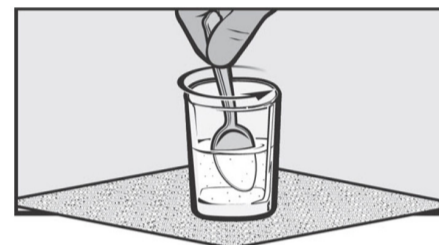


Figure CC



Figure DD

If your total prescribed dose is more than 10 mg, repeat steps 4 through 10 to finish taking your dose.

Step 11: Wash the glass and the spoon thoroughly with water. Wipe the glass and spoon with a clean paper towel and store them in a dry and clean place until your next dose of everolimus tablets for oral suspension (see Figure EE).

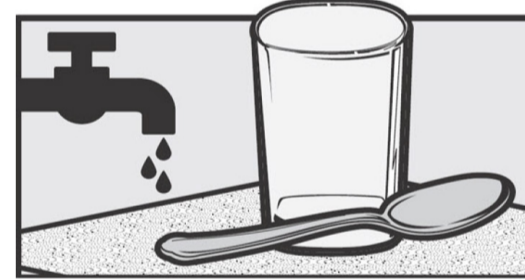


Figure EE

Step 12: Throw away the used paper towel and gloves in your household trash.

Step 13: Wash your hands.

How should I store everolimus tablets for oral suspension?

- Store everolimus tablets for oral suspension at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep everolimus tablets for oral suspension in the pack it comes in.
- Open the blister pack just before taking everolimus tablets for oral suspension.
- Keep everolimus tablets for oral suspension dry and away from light.
- Do not use everolimus tablets for oral suspension that is out of date or no longer needed.

Keep everolimus tablets for oral suspension and all medicines out of the reach of children.

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

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Natco Pharma Limited
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