

Instructions for Use

ISENTRESS® (eye sen tris) (raltegravir) for oral suspension

Read this Instructions for Use before you mix and give a dose of ISENTRESS for oral suspension to your child for the first time, and each time you get a refill. There may be new information. These instructions will help you to correctly mix and give a dose of ISENTRESS for oral suspension to your child.

See the Patient Information leaflet that comes with ISENTRESS for oral suspension for more information about ISENTRESS.

Your doctor will decide the right dose based on your child's weight.

Ask your doctor or pharmacist if you have any questions about how to mix or give ISENTRESS for oral suspension to your child.

Each ISENTRESS for oral suspension kit contains the following supplies (see Figure A):

- 2 reusable mixing cups with attached lids
- 2 reusable 5 mL dosing syringes
- 60 foil packets containing ISENTRESS for oral suspension

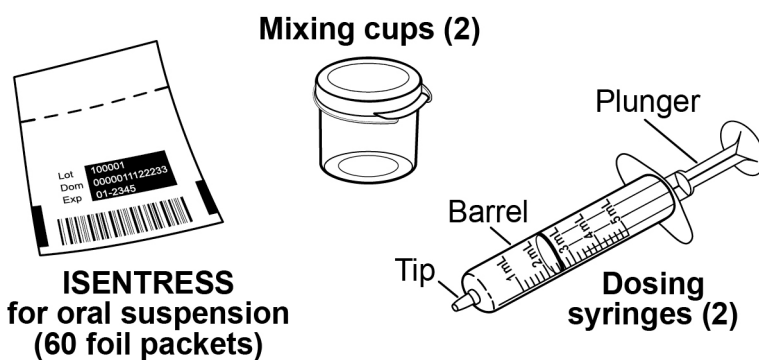


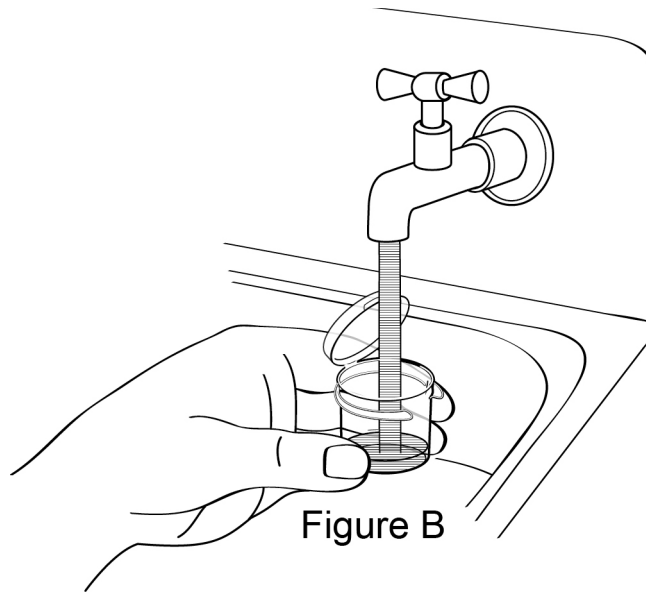
Figure A

For each dose of ISENTRESS for oral suspension you will need the following:

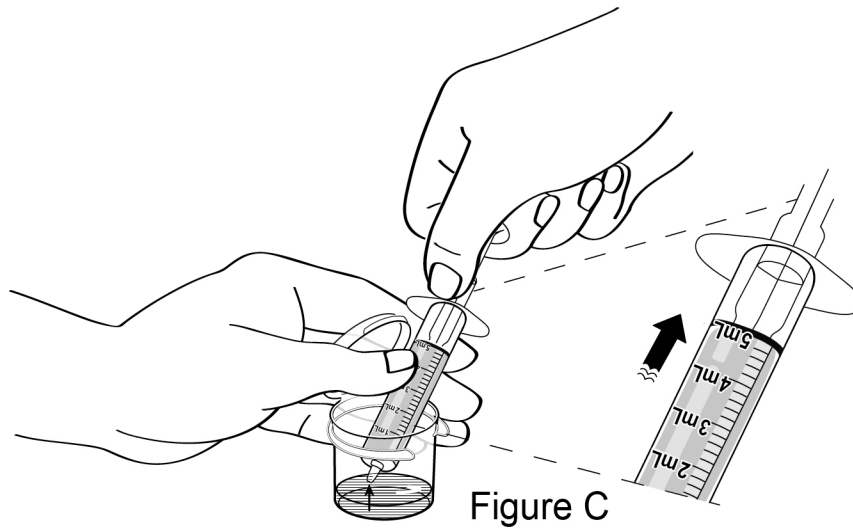
- 1 mixing cup with attached lid
- 1 dosing syringe (5mL)
- 1 foil packet containing the medicine
- Drinking water (not included in kit)

How do I prepare a dose of ISENTRESS for oral suspension?

Step 1. Fill mixing cup about half-way with drinking water (see Figure B).



Step 2. Fill the dosing syringe. Start with the plunger pushed all the way inside the barrel of the syringe. Insert the tip of the syringe into the water and pull back on the plunger to the 5 mL marking on the barrel of the syringe (see Figure C).



Step 3. Pour out remaining water from mixing cup (see Figure D).

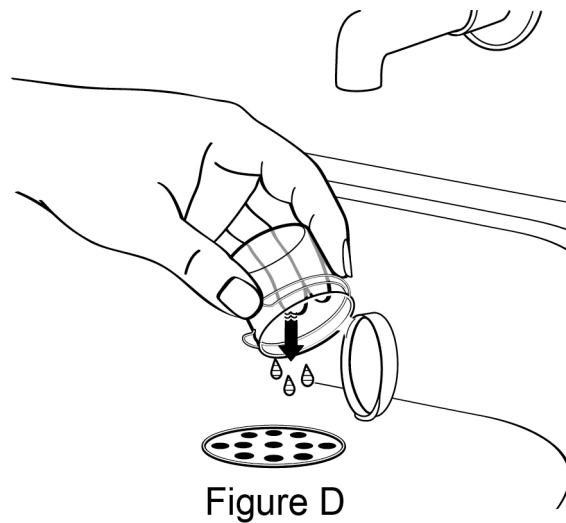


Figure D

Step 4. Add the 5 mL of water from the dosing syringe back into the mixing cup by pressing down on the plunger (see Figure E).

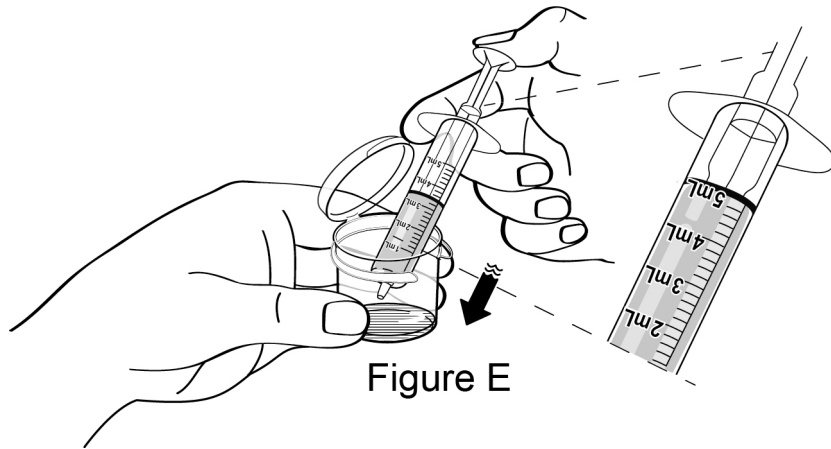


Figure E

Step 5. Open 1 foil packet. There is a notch that you can use to tear open the foil packet, or you may use scissors to cut along the dotted line. Pour entire contents into mixing cup (see Figure F).

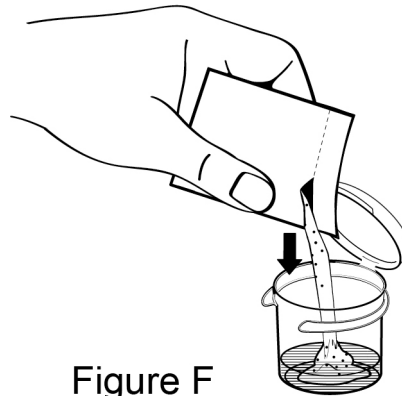


Figure F

Step 6. Close the attached lid to seal the mixing cup (see Figure G). It will snap shut.

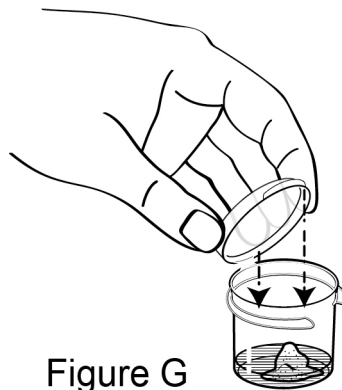


Figure G

Step 7. Swirl the mixing cup to mix using a gentle circular motion for 30-60 seconds (see Figure H). **Do not** turn the mixing cup upside down. The liquid will be cloudy.



Figure H

Step 8. Open the mixing cup. Put the tip of the syringe into the liquid and **pull back the plunger to the mL marking that matches your child's prescribed dose** (see Figure I). Your child's dose may be different from the one shown in the figure.

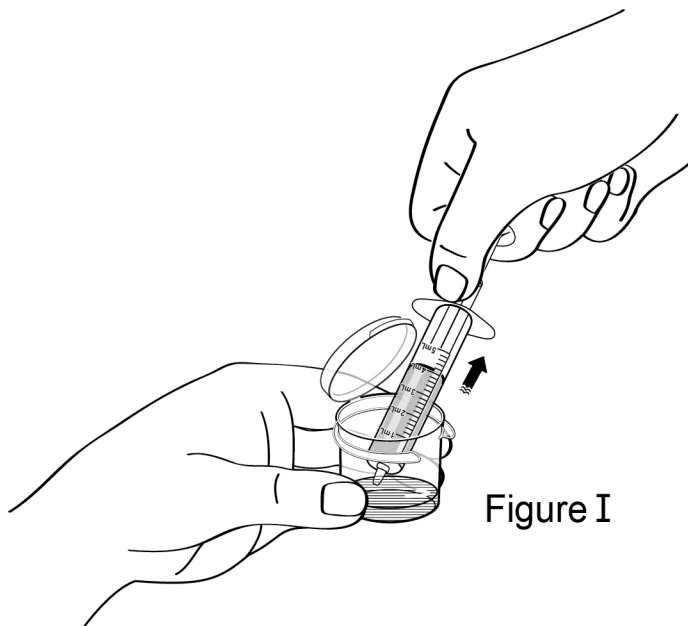


Figure I

How should I give a dose of ISENTRESS for oral suspension?

Step 9. Place the tip of the dosing syringe in your child's mouth and turn it toward either cheek. Gently push down on the plunger to give the medicine (see Figure J). Give the dose of ISENTRESS oral suspension to your child within 30 minutes of mixing. If you are not able to give your child's dose within 30 minutes of mixing, pour the unused medicine into the trash. You will need to mix a new dose.

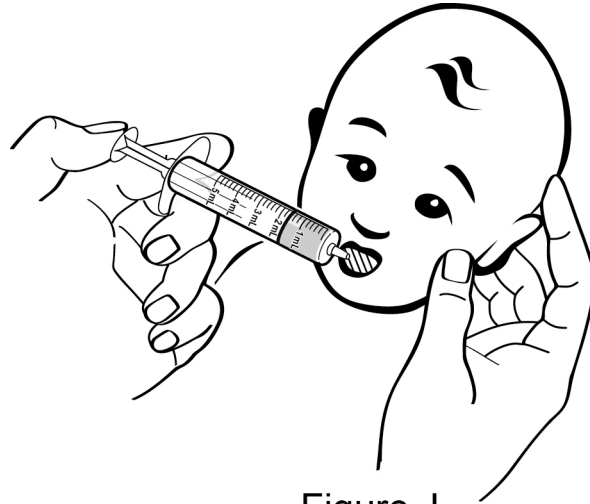


Figure J

How should I dispose of leftover ISENTRESS for oral suspension?

Step 10. Pour any leftover medicine from the mixing cup into the trash (see Figure K).

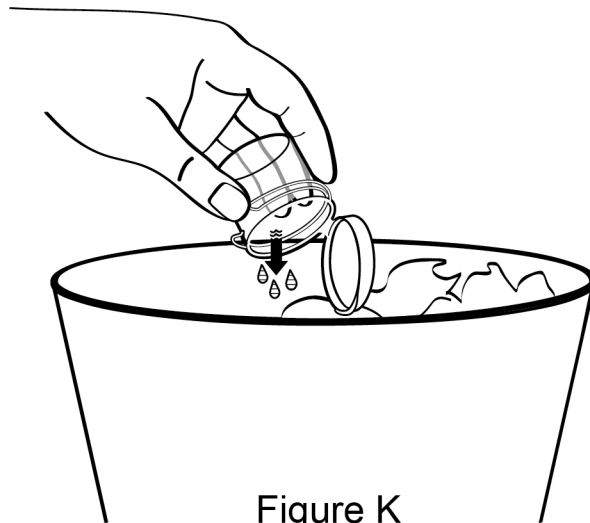
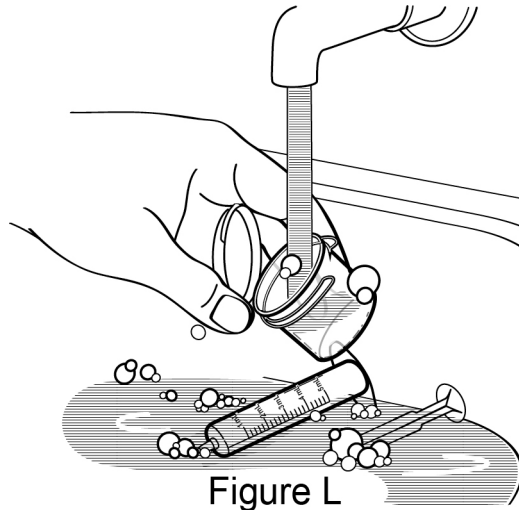


Figure K

Step 11. Remove plunger from the barrel of the dosing syringe. Hand wash the dosing syringe and mixing cup with warm water and dish soap. Rinse with water and air dry (see Figure L).



How should I store ISENTRESS for oral suspension?

- Store ISENTRESS for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Store in the original container. Do not open the foil packets until ready for use.

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

For more information go to www.ISENTRESS.com or call 1-800-622-4477.

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

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