

Instructions for Use
REYATAZ® (RAY-ah-taz)
(atazanavir)
oral powder

Read this Instructions for Use before you prepare your child's first dose of REYATAZ oral powder, each time you get a refill, and as needed. There may be new information. This information does not take the place of talking to your child's healthcare provider about their medical condition or treatment. Ask your child's healthcare provider or pharmacist if you have questions about how to mix or give a dose of REYATAZ oral powder.

Important information:

- For more information about REYATAZ oral powder, see the Patient Information leaflet.
- REYATAZ oral powder must be mixed with food or liquid. If REYATAZ oral powder is mixed with water, your child must eat food right after taking REYATAZ oral powder.
- REYATAZ oral powder must be taken with ritonavir.
- Talk with your child's healthcare provider to help decide the best schedule for giving your child REYATAZ oral powder.

Instructions for mixing REYATAZ oral powder:

REYATAZ oral powder should be mixed with food such as applesauce or yogurt, instead of a liquid (milk, infant formula, or water) in young children and infants who can take food.

- Infants less than 6 months old and who cannot eat solid food or drink from a cup should be given REYATAZ oral powder mixed with infant formula using an oral dosing syringe.
- REYATAZ oral powder that is mixed in infant formula or liquid should not be given using a baby bottle.

When preparing REYATAZ oral powder with either food or liquid, choose a clean, flat work surface. Place a clean paper towel on the work surface. Place the supplies you will need on the paper towel.

Wash and dry your hands before and after preparing REYATAZ oral powder.

Preparing a dose of REYATAZ oral powder mixed with food:

Before you prepare a dose of REYATAZ oral powder mixed with food, gather the following supplies:

- paper towel
- tablespoon
- **small** clean container (such as a **small** cup or bowl)
- a food such as applesauce or yogurt
- the correct number of packets of REYATAZ oral powder needed for the prescribed dose
- a clean pair of scissors

Step 1. Place at least 1 tablespoon of a food such as applesauce or yogurt in the small container (see Figure A).

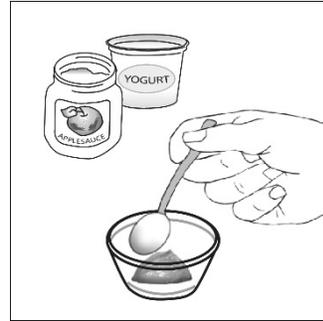


Figure A

Step 2. Tap the packet of REYATAZ oral powder to settle the contents to the bottom of the packet (see Figure B).

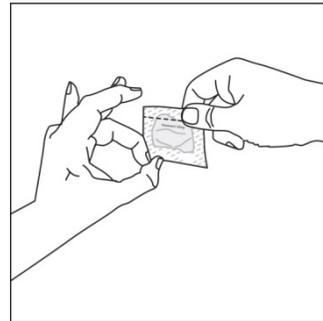


Figure B

Step 3. Using a clean pair of scissors, cut open the packet on the dotted line (see Figure C).

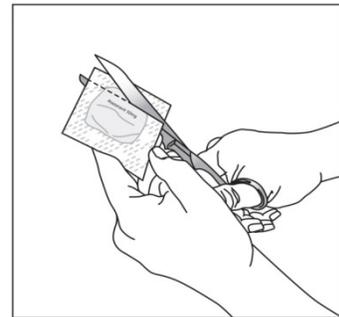


Figure C

Step 4. Empty the contents of the packet into the small container onto the food (see Figure D).

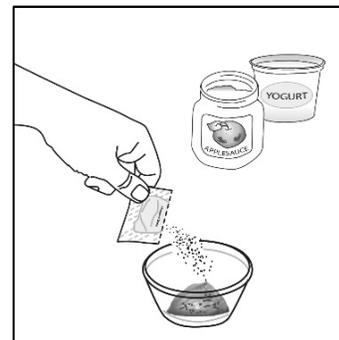


Figure D

Repeat Steps 2 through 4 for each packet of REYATAZ oral powder needed for the total prescribed dose.

Step 5. Use a tablespoon to gently mix the powder and the food together (see Figure E).

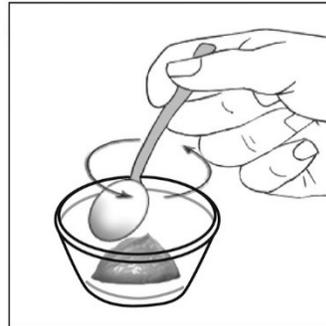


Figure E

Steps 6 through 8 must be completed **within 1 hour** of mixing the medicine.

Step 6. Use the tablespoon or a small spoon to feed the REYATAZ oral powder and food mixture to your child. Look in your child's mouth to make sure that all of the mixture is swallowed.

Step 7. Add 1 tablespoon more of food to the empty container and gently stir to mix with any contents that may still be in the container.

Step 8. Use the tablespoon or a small spoon to feed your child the mixture, making sure your child has swallowed all of the mixture.

Step 9. Give your child ritonavir as prescribed right after taking REYATAZ oral powder.

Step 10. Wash the container and tablespoon. Allow the container and spoon to dry. Throw away the paper towel and clean the work surface.

Preparing a dose of REYATAZ oral powder mixed with liquid in a small drinking cup:

Before you prepare a dose of REYATAZ oral powder mixed with liquid in a small drinking cup, gather the following supplies:

- paper towel
- spoon
- 30 milliliter (mL) medicine cup (ask your pharmacist for this). See Figure F.
- small drinking cup
- liquid such as milk or water
- the correct number of packets of REYATAZ oral powder needed for the prescribed dose
- a clean pair of scissors

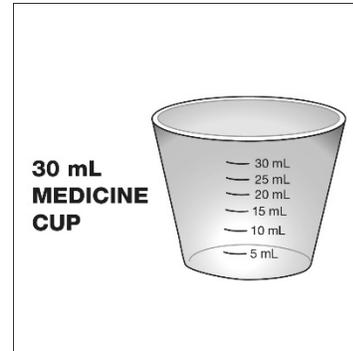


Figure F

Step 1. Using the 30 mL medicine cup, pour at least 30 mL of liquid into the small drinking cup (see Figure G).

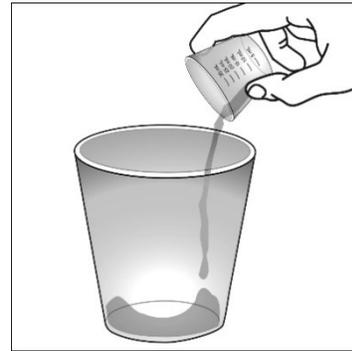


Figure G

Step 2. Tap the packet of REYATAZ oral powder to settle the contents to the bottom of the packet (see Figure H).

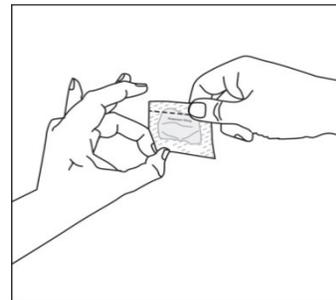


Figure H

Step 3. Using a clean pair of scissors, cut open the packet on the dotted line (see Figure I).

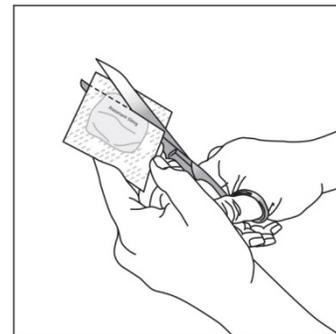


Figure I

Step 4. Empty the contents of the packet into the small drinking cup (see Figure J).



Figure J

Repeat Steps 2 through 4 for each packet of REYATAZ oral powder needed for the total prescribed dose.

Step 5. Hold the small drinking cup with one hand. With your other hand, use the spoon to gently mix the powder and the liquid (see Figure K).



Figure K

Steps 6 and 7 must be completed **within 1 hour** of mixing the medicine.

Step 6. Have your child drink all of the mixture in the small drinking cup.

Step 7. To make sure there is no mixture left in the small drinking cup add 15 mL more liquid to the small drinking cup:

- Stir with the spoon.
- **Repeat Step 6 above.**

If REYATAZ oral powder is mixed with water, your child must eat food right after taking REYATAZ oral powder.

Step 8. Give your child ritonavir as prescribed right after taking REYATAZ oral powder.

Step 9. Wash the small drinking cup, medicine cup, and spoon. Allow the small drinking cup, medicine cup, and spoon to dry. Throw away the paper towel and clean the work surface.

Preparing a dose of REYATAZ oral powder mixed with liquid infant formula using an oral dosing syringe and a small medicine cup:

Before you prepare a dose of REYATAZ oral powder mixed with infant formula using an oral dosing syringe, gather the following supplies:

- paper towel
- small spoon
- 30 milliliter (mL) medicine cup (ask your pharmacist for this). See Figure L.
- 10 mL oral dosing syringe (ask your pharmacist for this). See Figure L.
- infant formula
- the correct number of packets of REYATAZ oral powder needed for the prescribed dose
- a clean pair of scissors

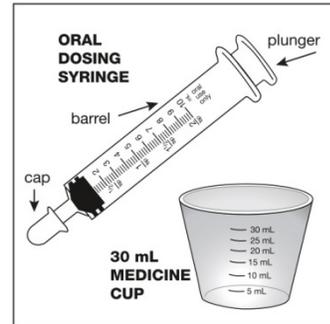


Figure L

Step 1. Prepare the infant formula according to the directions on the infant formula package.

Step 2. Pour 10 mL of infant formula into the medicine cup (see Figure M).

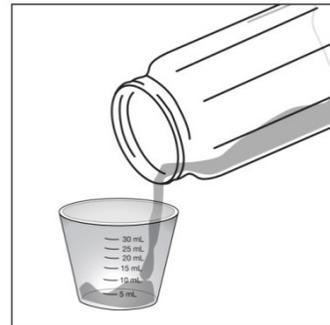


Figure M

Step 3. Tap the packet of REYATAZ oral powder to settle the contents to the bottom of the packet (see Figure N).

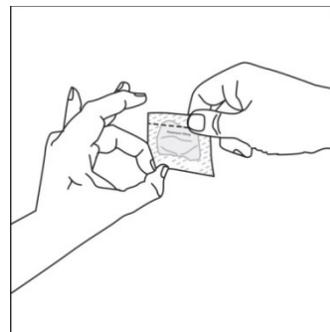


Figure N

Step 4. Using a clean pair of scissors, cut open the packet on the dotted line (see Figure O).

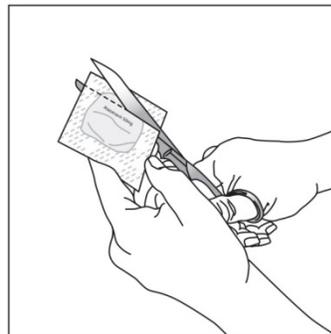


Figure O

Step 5. Empty the contents of the packet into the medicine cup (see Figure P).

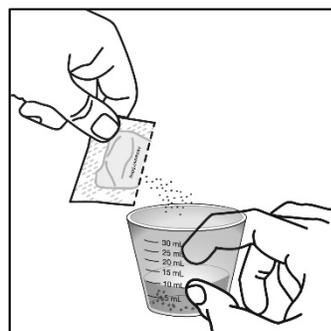


Figure P

Repeat Steps 3 through 5 for each packet of REYATAZ oral powder needed for the total prescribed dose.

Step 6. Hold the medicine cup with one hand. With your other hand, use the small spoon to gently mix the powder and the infant formula (see Figure Q).



Figure Q

Steps 7 through 9 must be completed **within 1 hour** of mixing the medicine.

Step 7. Draw up the powder and infant formula mixture into the oral dosing syringe as follows:

- Check that the plunger is completely pushed into barrel of the syringe (see Figure R).

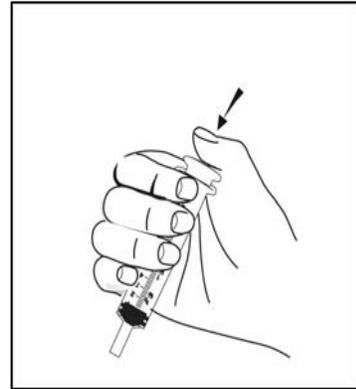


Figure R

- Place the tip of the syringe into the powder and infant formula mixture in the medicine cup (see Figure S).

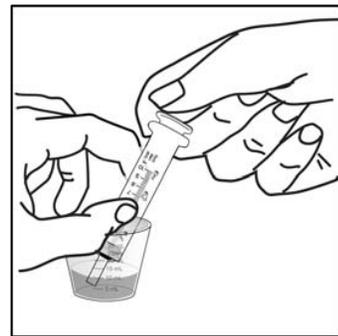


Figure S

- Slowly pull back on the plunger and draw up 10 mL of the mixture (see Figure T).

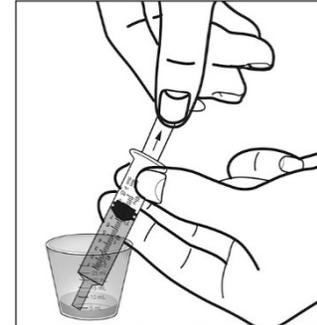


Figure T

Step 8. Place the tip of the oral dosing syringe in your baby's mouth along the inner cheek on either the right or left side (see Figure U). Slowly push on the plunger to give your baby all of the REYATAZ oral powder and infant formula mixture.

- Draw up any remaining mixture with the oral dosing syringe and repeat until all of the mixture has been given to the baby.

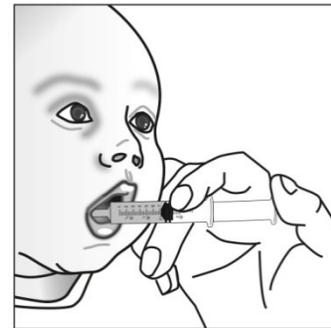


Figure U

Step 9. To make sure there is no mixture left in the medicine cup or syringe:

- Repeat Step 1 above to add 10 mL more infant formula to the medicine cup.
- Stir with a small spoon.
- **Then repeat Steps 7 through 8 above.**

To make sure that your baby gets all of the medicine, do not give REYATAZ oral powder in a baby bottle.

Step 10. Give your baby ritonavir as prescribed right after taking REYATAZ oral powder.

Step 11. Remove the plunger from the oral dosing syringe. Wash the medicine cup, spoon, and oral dosing syringe. Allow the medicine cup, spoon, and oral dosing syringe to dry. Throw away the paper towel and clean the work surface.

How should I store REYATAZ oral powder?

- Store REYATAZ oral powder at a temperature of 68°F to 86°F (20°C to 30°C).
- Store REYATAZ oral powder in the original packet. Do not open until ready to use.
- After REYATAZ oral powder is mixed with food or liquid, it may be kept at a temperature of 68°F to 86°F (20°C to 30°C) for up to 1 hour. Take REYATAZ oral powder within 1 hour after mixing with food or liquid.

Keep REYATAZ oral powder 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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