

INSTRUCTIONS FOR USE
RADICAVA (ra di ká vah) ORS
(edaravone)
oral suspension

Read this Instructions for Use before you take RADICAVA ORS for the first time 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 about measuring RADICAVA ORS: Always measure your prescribed dose of RADICAVA ORS using the oral syringe provided. Ask your healthcare provider or pharmacist who provided the medicine any question you have about how to measure your prescribed dose. If you miss a dose, **do not** take 2 doses of RADICAVA ORS the next day. **Do not** take a dose of RADICAVA ORS on days 15 through day 28.

How to prepare RADICAVA ORS: Keep this Instructions for Use handy when preparing the treatment.

- If your healthcare provider prescribes a Starter Kit, you will receive 2 bottles of RADICAVA ORS. Each bottle will contain 35 mL of RADICAVA ORS for a total of 70 mL to be used for your first treatment cycle of 14 days. **Only open the second bottle when you have finished the first bottle.**
- If you were not prescribed the Starter Kit, for each treatment cycle you will receive 1 bottle of RADICAVA ORS that contains a total of 50 mL of RADICAVA ORS. After the first treatment cycle, RADICAVA ORS is to be used for 10 days out of 14 day periods.
- Only use the bottle adapter and the 2 reusable 5mL oral syringes provided with the bottle. **Do not** use a household teaspoon to measure your medicine.

How to store RADICAVA ORS:

- Store RADICAVA ORS upright at room temperature between 68°F to 77°F (20°C to 25°C). Protect from light.
- **Opening the bottle:**
 - When you open the bottle of RADICAVA ORS for the first use, write the date you open the bottle on the bottle label.
 - After opening the bottle of RADICAVA ORS, use within 15 days.
- After a bottle of Radicava ORS has been opened and used, a white crust may form on the neck or on the side of the bottle. This is due to normal use and RADICAVA ORS can continue to be used as prescribed.
- **Keep bottle tightly closed between each use.**
- **Throw away (discard) any RADICAVA ORS that is not used within 15 days after opening the bottle or within the 30 days from the date of shipment shown on the carton pharmacy label, which ever happens first.** Ask your pharmacist how to properly throw away (discard) RADICAVA ORS you are no longer able to use.
- **Keep RADICAVA ORS and all medicines out of the reach of children.**

Each RADICAVA ORS carton contains:

- 1 RADICAVA ORS bottle
- 1 bottle adapter
- 2 (5 mL) reusable oral syringes

Use a new 5 mL oral syringe and bottle adapter when using a new bottle of RADICAVA ORS (see Figure A).

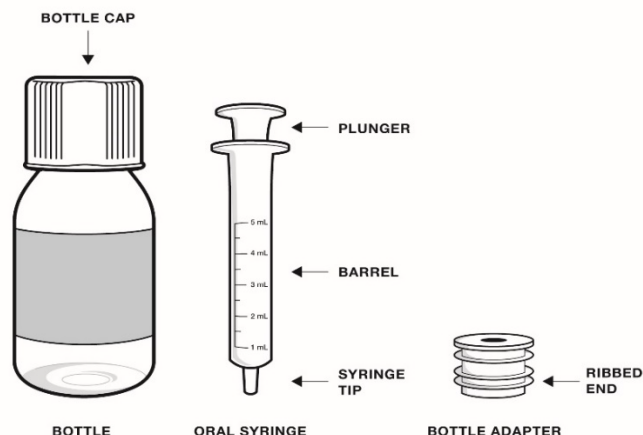


Figure A

Important information:

- Keep these instructions for future use.
- Do not share RADICAVA ORS with anyone else.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
- People who have problems using their hands may need assistance to draw up and give the correct dose of RADICAVA ORS.

How to take RADICAVA ORS:

Take RADICAVA ORS as prescribed by your healthcare provider.

Dosing Information:

RADICAVA ORS has 2 different dosing schedules:

- For the first treatment cycle, you will take RADICAVA ORS every day for 14 days, followed by 14 days without the medicine.
- For the cycles after the first treatment cycle, you will take RADICAVA ORS daily for 10 out of 14 days, followed by 14 days without the medicine.

How RADICAVA ORS will be provided:

- If your healthcare provider prescribes the Starter Kit, you will receive 2 bottles of RADICAVA ORS. Each bottle contains 35 mL of RADICAVA ORS for a total of 70 mL to deliver 14 doses.
 - There may be some medicine that remains in each bottle after the dose on day 7 and day 14 of the first treatment cycle. Throw away (discard) any medicine that remains.
- If you were not prescribed the starter kit, for each treatment cycle, you will receive 1 bottle of RADICAVA ORS that contains a total of 50 mL of RADICAVA ORS to deliver 10 doses.
 - There may be some medicine that remains in each bottle after 10 doses. Throw away (discard) any medicine that remains.

Fasting Information:

- **Do not** eat or drink anything 8 hours before each dose of RADICAVA ORS if you eat a high-fat meal.
- **Do not** eat or drink anything 4 hours before each dose of RADICAVA ORS if you eat a low-fat meal.
- **Do not** eat or drink anything 2 hours before each dose of RADICAVA ORS if you take a calorie supplement.
- You should wait at least 1 hour after taking your medicine before eating or drinking anything except water.

Step 1 – Before each use of RADICAVA ORS: Before opening the bottle, turn it upside down (invert) and shake vigorously up and down for at least **30 seconds** (see Figure B). Look at the liquid medicine to make sure it is mixed well. If you see any small pieces at the bottom of the bottle, invert the bottle and shake it up and down for another **30 seconds** or until you can no longer see the pieces at the bottom of the bottle (see Figure B). If the liquid medicine all looks the same, you can proceed to Step 2.

Shake up and down for
at least 30 seconds

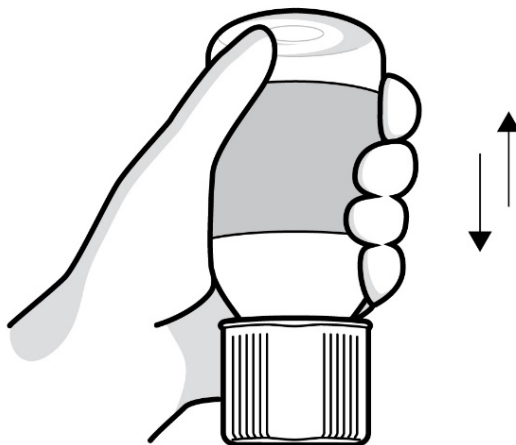


Figure B

Step 2: Open the bottle by **firmly pressing down** on the bottle cap and turning it counterclockwise (to the left). Place the open bottle upright on a flat surface. **Do not** throw away the bottle cap, you will need to replace it after taking each dose.

First time use of a bottle only. This must only be done 1 time for each bottle. Insert the ribbed end of the bottle adapter into the bottle by firmly pressing it in as far as it will go (see Figure C). **Do not** remove the bottle adapter.

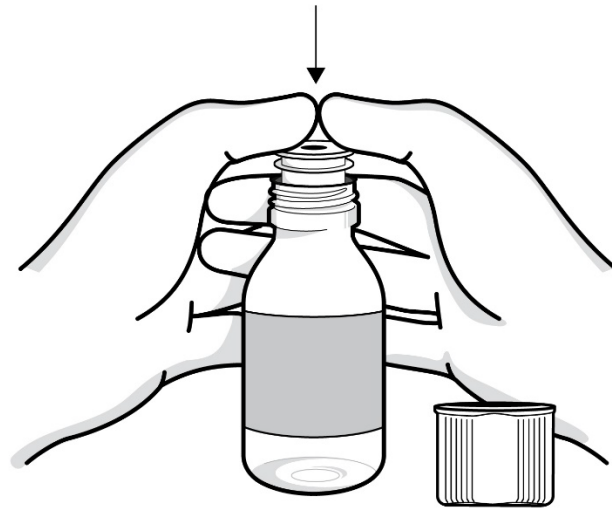


Figure C

Step 3: Remove the oral syringe from plastic wrap and make sure the plunger is inserted all the way into the barrel. Push the oral syringe plunger toward its tip to remove excess air (see Figure D). Insert the oral syringe into the opening of the bottle adapter until it is firmly in place (see Figure E). Turn the bottle upside down and slowly pull the plunger to remove a small amount of liquid (see Figure F).

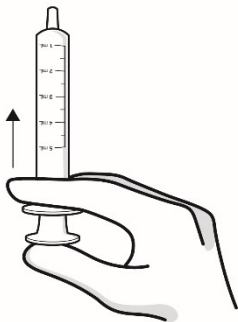


Figure D

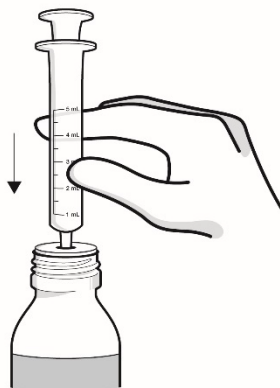


Figure E

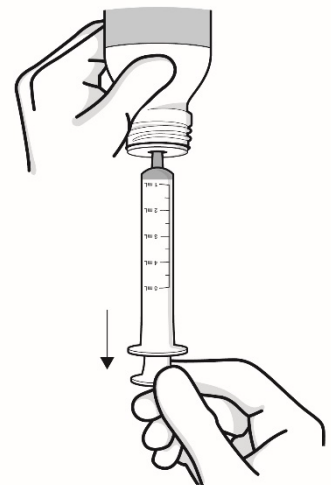


Figure F

Step 4: Keep the bottle upside down and pull the plunger until it goes up to the last line (5 mL) (see Figure G). While keeping the plunger in the same position, turn the bottle upright, and place it carefully on a flat surface. Remove the oral syringe by gently twisting or pulling it out from the bottle (see Figure H). Check the amount of medicine again before moving on to the next step (see Figure I).

Note: **Do not** remove the oral syringe while the bottle is upside down (medicine may leak out through the adapter).

Note: If the dose is not correct, insert the oral syringe tip firmly into the bottle adapter. Push the plunger all the way in so that the medicine flows back into the bottle. Turn the bottle upside down. Repeat Step 4.

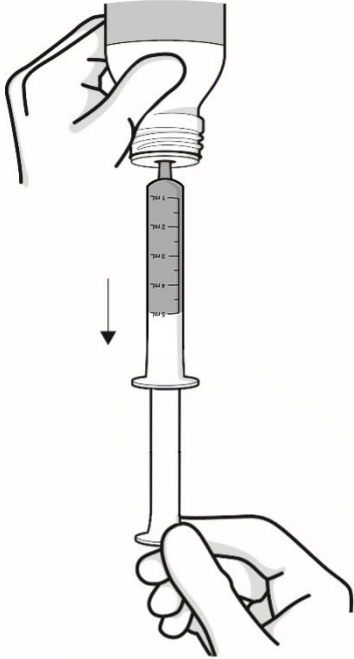


Figure G

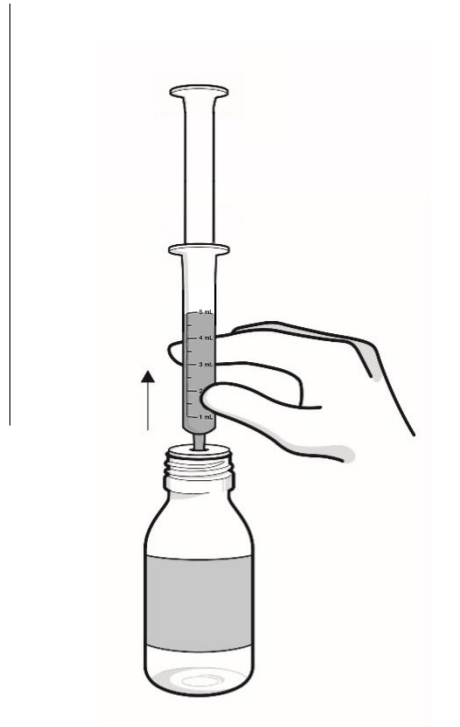


Figure H

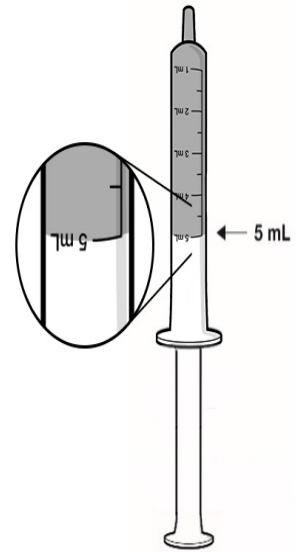


Figure I

Step 5: Place the tip of the oral syringe in the mouth and aim towards the inside of the cheek. Slowly press down on the plunger until the oral syringe is empty. Swallow all of the medicine (see Figure J). If needed, you can use up to 8 ounces or 1 cup of water to help swallow the medicine.

Note: It is normal for a small amount of medicine to remain in the tip of the syringe after taking.



Figure J

Step 6: Leave the bottle adapter inside the bottle. Place the bottle cap on the bottle and turn the cap clockwise (to the right). Keep bottle tightly closed between each use (see Figure K).

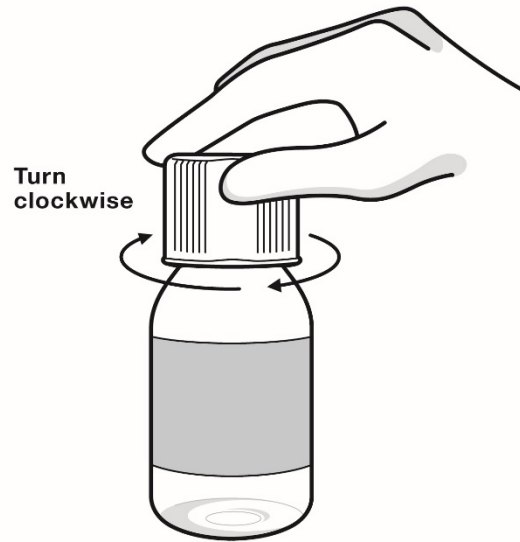


Figure K

Step 7: Remove the plunger from the oral syringe barrel by pulling the plunger and the barrel away from each other. **Rinse the oral syringe (plunger and barrel) with water only.** Allow it to air dry.

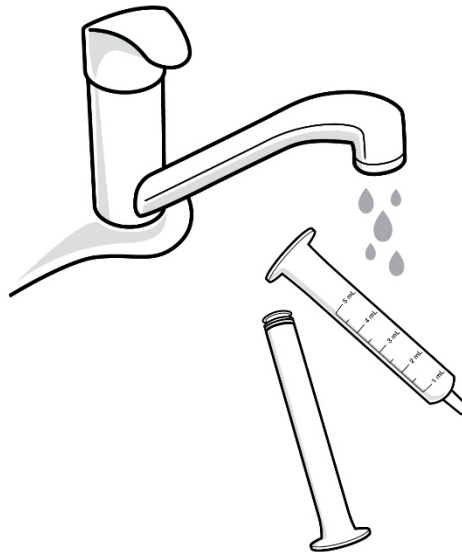


Figure L

Step 8: When the oral syringe (plunger and barrel) are dry, put the plunger back into the oral syringe barrel. **Do not throw away the oral syringe.** Store the syringe in a clean, dry place.

You must complete Steps 1 through 4 under "How to take RADICAVA ORS" before starting Step 9 under "How to take a dose of RADICAVA ORS oral suspension through a feeding tube."

How to take a dose of RADICAVA ORS oral suspension through a feeding tube:

Step 9. Using a catheter-tip syringe, flush the feeding tube with 1 ounce (30 mL) of water (see Figure M).

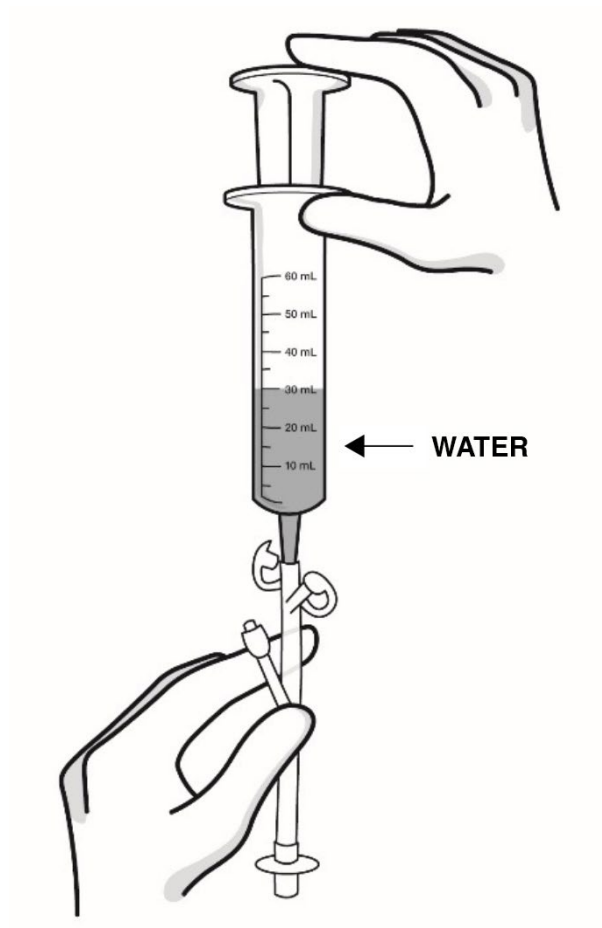


Figure M

Step 10. Place the oral syringe provided (containing the 5 mL of RADICAVA ORS) into the feeding tube. Slowly push down the plunger until the oral syringe is empty (see Figure N).

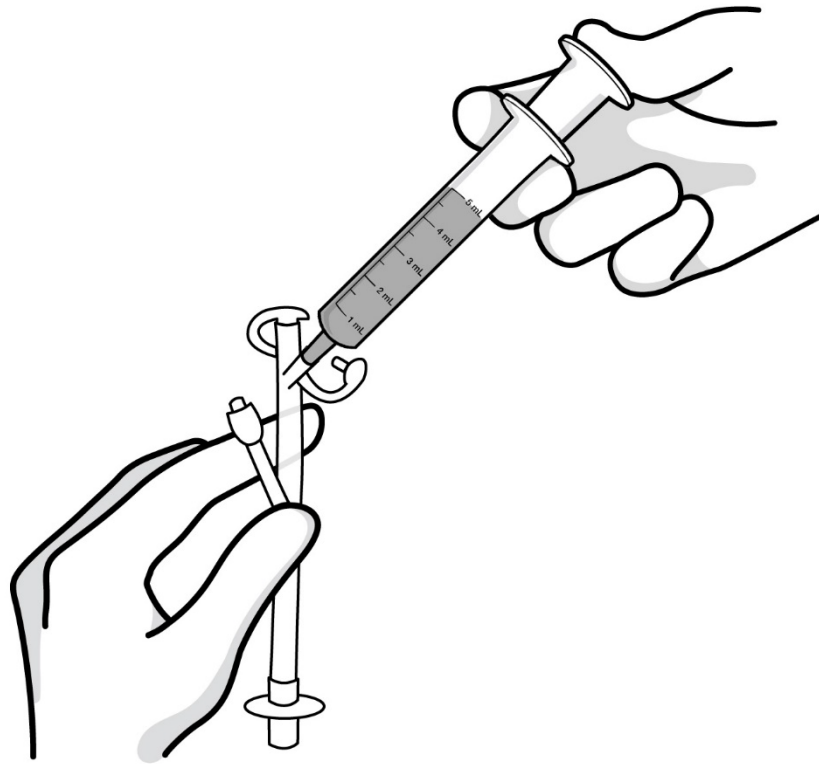


Figure N

Step 11. Using a catheter-tip syringe, flush the feeding tube with 1 ounce (30 mL) of water after taking the dose of RADICAVA ORS (see Figure O).

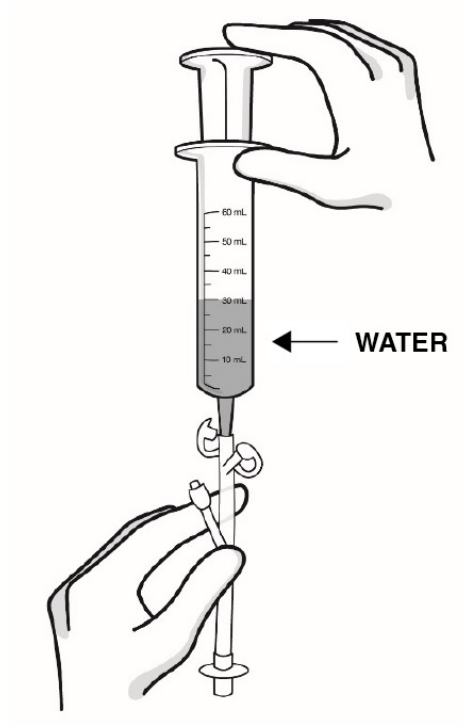


Figure O

Step 12. Leave the adapter in the bottle. Place the bottle cap on the bottle and turn it clockwise (to the right) to close the bottle. Keep the bottle tightly closed between each use (see Figure P).

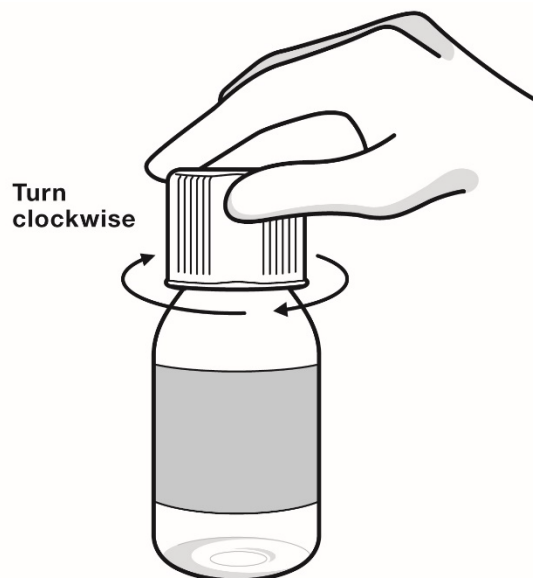


Figure P

Step 13. Remove the plunger from the oral syringe barrel by pulling the plunger and barrel away from each other. Rinse the oral syringe (plunger and barrel) with water only (see Figure Q). Allow it to air dry.



Figure Q

Step 14. When the oral syringe (plunger and barrel) are dry, put the plunger back into the oral syringe barrel. **Do not throw away the oral syringe.** Store the oral syringe in a clean, dry place.

Marketed and distributed by:

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Jersey City, NJ 07310

For more information, go to www.Radicava.com or call 1- 888-292-0058.

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