

Pr Radicava[®] Oral Suspension
(edaravone) 105 mg / 5 mL

Your RADICAVA[®] Oral Suspension dosing and administration guide



Mitsubishi Tanabe Pharma Canada

This booklet provides an overview of the steps associated with the dosing and administration of RADICAVA® Oral Suspension. For more information and to view the dosing videos, please visit **RADICAVA.ca** or scan the QR code below.

Scan to view the **RADICAVA® Oral Suspension dosing and administration video.**



How to take RADICAVA® Oral Suspension

RADICAVA® Oral Suspension has two dosing cycles – one for the first cycle if you are starting treatment with RADICAVA® Oral Suspension (and have not taken RADICAVA® IV Infusion before), and one for all of the subsequent cycles (cycles 2+), including if you are switching from RADICAVA® IV.

Take RADICAVA® Oral Suspension as prescribed by your healthcare provider.

Dosing schedule

Treatment with Starter Dosing Kit



14 consecutive days on
14 consecutive days off

- If you are taking RADICAVA® Oral Suspension for the first time, you will be prescribed the Starter Dosing Kit. With this schedule, you will take RADICAVA® Oral Suspension for 14 days followed by 14 days without taking the medication.
- In the Starter Dosing Kit you will receive two bottles, each containing 35 mL of RADICAVA® Oral Suspension
 - This is a total of 70 mL to deliver 14 doses
- There may be some product that remains in each bottle after the dose on Day 7 and Day 14
 - Discard any excess medicine

Dosing Kit for subsequent treatments



10 out of 14 days on
14 consecutive days off

- If you have completed your first treatment cycle with RADICAVA® Oral Suspension or are switching from RADICAVA® IV, you will be prescribed the Dosing Kit. With this schedule, you will take RADICAVA® Oral Suspension daily for any 10 days out of a 14-day period, followed by 14 days without taking the medication.
- The Dosing Kit contains one bottle with 50 mL of RADICAVA® Oral Suspension, for 10 doses
- There may be some product that remains in the bottle after 10 doses

When to take RADICAVA® Oral Suspension

RADICAVA® Oral Suspension should be taken in the morning on an empty stomach after not eating (fasting) overnight for 8 hours.

- Wait for at least **1 hour** before eating or drinking anything, except water

If you are unable to fast overnight before your morning dose, you can reduce the fasting time to:

- **4 hours** before each dose if you eat a **low-fat meal** (400–500 calories, 25% fat)
- **2 hours** before each dose if you take a **calorie supplement** (250 calories, e.g., protein drink)

RADICAVA® Oral Suspension is to be taken orally or through a feeding tube.

IMPORTANT INFORMATION

- Always administer RADICAVA® Oral Suspension using the oral syringe that comes with the product
 - Do not use a household teaspoon to measure your medicine
- Ask your healthcare provider or pharmacist any questions you may have about how to measure your prescribed dose
- If you miss a dose, take it as soon as possible if it is the same day
- Never take two doses of RADICAVA® Oral Suspension on the same day to make up for a missed dose
- Do not take a dose of RADICAVA® Oral Suspension on days 15 through 28 of the dosing cycle
- Do not share RADICAVA® Oral Suspension with anyone else
- If you experience side effects, consult your healthcare provider
- People who have problems using their hands may need assistance to draw up and give the correct dose of RADICAVA® Oral Suspension

How to prepare your dose

Each RADICAVA® Oral Suspension carton contains (see Figure A):

- 1 RADICAVA® Oral Suspension 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® Oral Suspension.

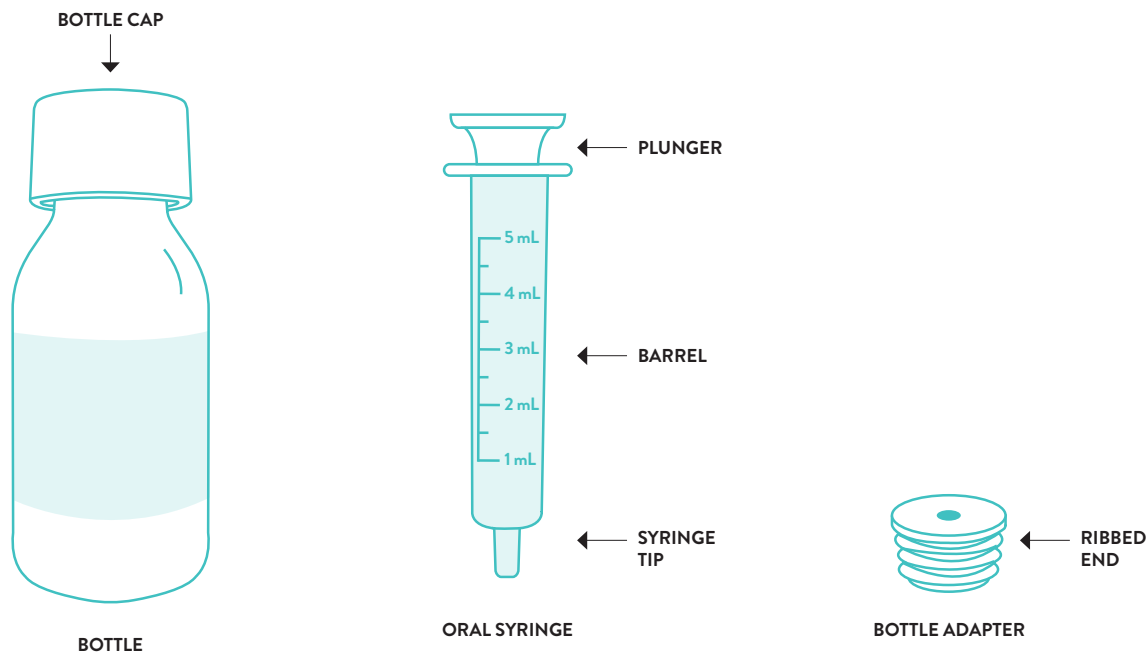


Figure A

When you open the bottle of RADICAVA® Oral Suspension for the first use, write the date on the bottle label. Throw away (discard) any RADICAVA® Oral Suspension that is not used within 15 days after opening the bottle or within 30 days from the date of shipment shown on the carton pharmacy label, whichever happens first.

Only open the second bottle when you have finished the first bottle.

Step 1: Shake for 30 seconds before use

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

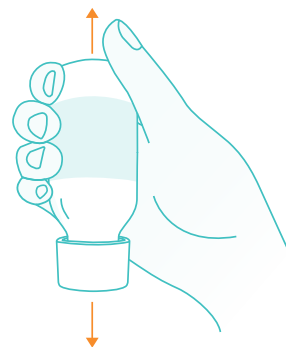


Figure B

Step 2: Insert adapter

- 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 as you will need to put it back on the bottle after taking each dose
- **For first time use of a 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 once it is inserted
 - The bottle cap will still fit with the adapter inside

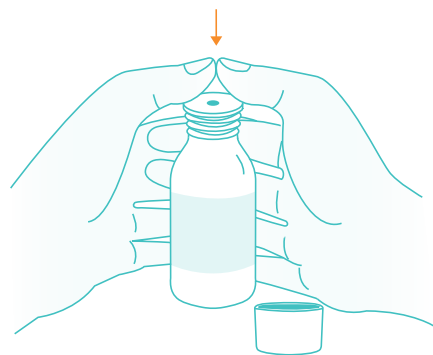


Figure C

NOTE: Only use the bottle adapter and 2 reusable 5 mL oral syringes provided with the bottle.

Step 3: Insert oral syringe

- Remove the oral syringe from the plastic wrap and make sure the plunger is inserted all the way into the barrel
- Push the plunger toward the tip of the oral syringe 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)

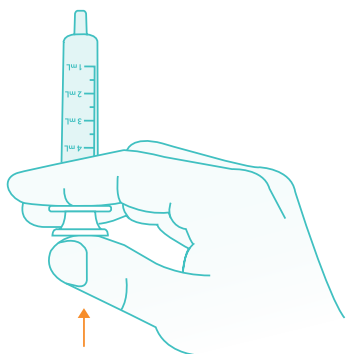


Figure D

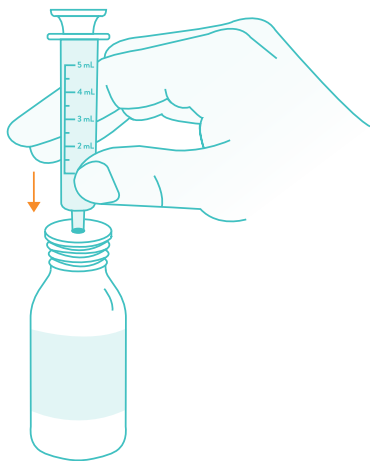


Figure E

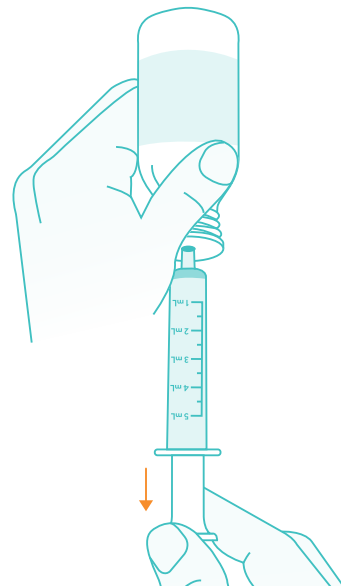


Figure F

NOTE: Always measure your prescribed dose of RADICAVA® Oral Suspension using the oral syringe provided.

Step 4: Fill to 5 mL and remove oral syringe

- Keep the bottle upside down and pull the plunger until it goes 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)
- Double-check the amount of medicine in the oral syringe before moving on to the next step (see Figure I)

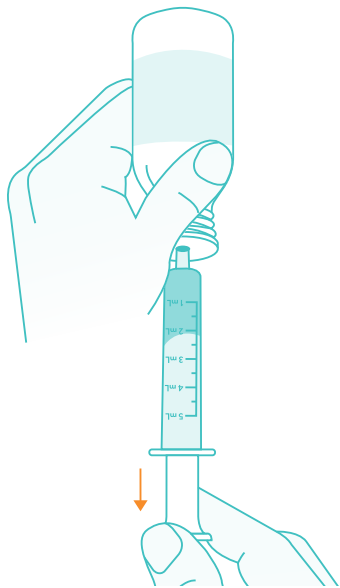


Figure G

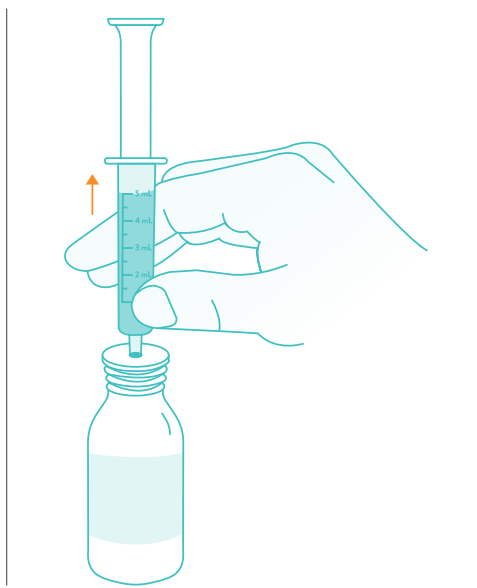


Figure H

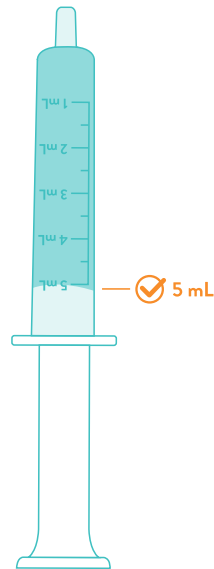


Figure I

NOTE: Do not remove the oral syringe while the bottle is upside down (as medicine may leak out from the adapter).

NOTE: If the dose is not correct, reinsert the tip of the oral syringe firmly into the bottle adapter and push the plunger all the way in so the medicine flows back into the bottle. Turn the bottle upside down and repeat Step 4.

Taking your medication orally: Steps 5–8

If you are taking RADICAVA® Oral Suspension through a feeding tube, please skip to the next section: *Taking your medication **with a feeding tube**: Steps 5-10*

Steps 5: Take medicine

- Place the tip of the oral syringe in the mouth and aim toward 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.

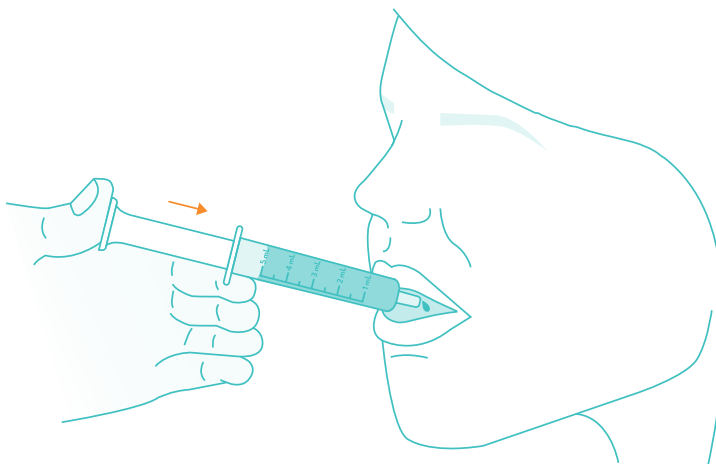


Figure J

Steps 6–8: Wash and store

Step 6:

Leave the bottle adapter inside the bottle and place the bottle cap on the bottle, turning the cap clockwise (to the right) to close. Keep bottle tightly closed between each use (see Figure K).

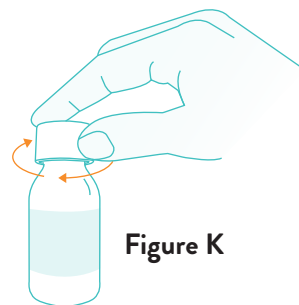


Figure K

Step 7:

Remove the plunger from the oral syringe barrel by pulling the plunger and the barrel away from each other. **Rinse the plunger and barrel with water only (see Figure L)** and allow them to air dry.

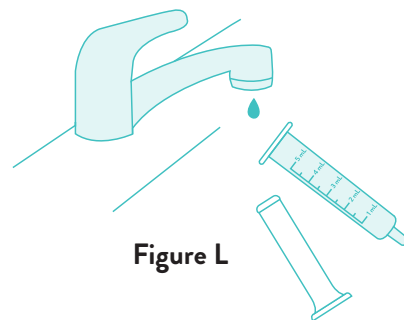
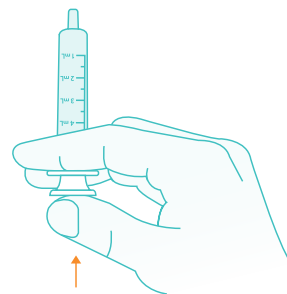


Figure L

Step 8:

When the 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.



The oral dosing instructions end here

Taking your medication with a feeding tube: Steps 5–10

You must complete Steps 1 through 4 under “How to take RADICAVA® Oral Suspension” before starting Step 5 under “Taking your medication with a feeding tube”

Step 5:

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

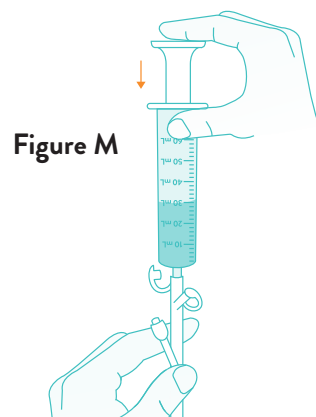


Figure M

Step 6:

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

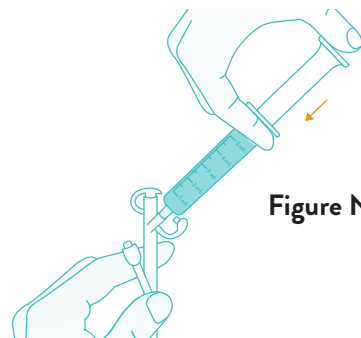


Figure N

Step 7:

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

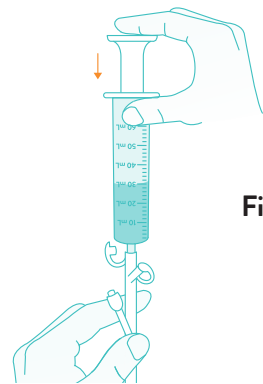


Figure O

Step 8:

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).

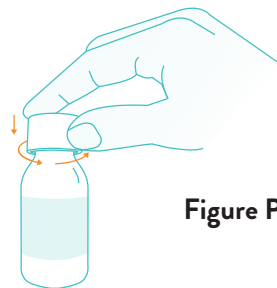


Figure P

Step 9:

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)** and allow them to air dry.

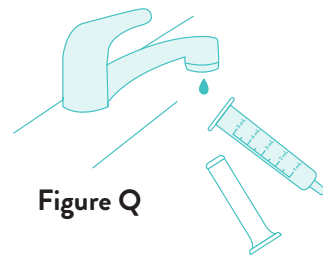


Figure Q

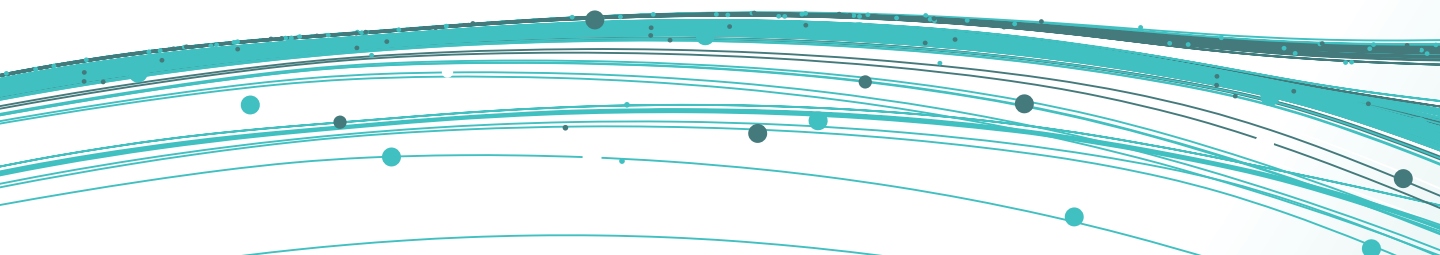
Step 10:

When the oral syringe (plunger and barrel) is 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.

How to store RADICAVA® Oral Suspension

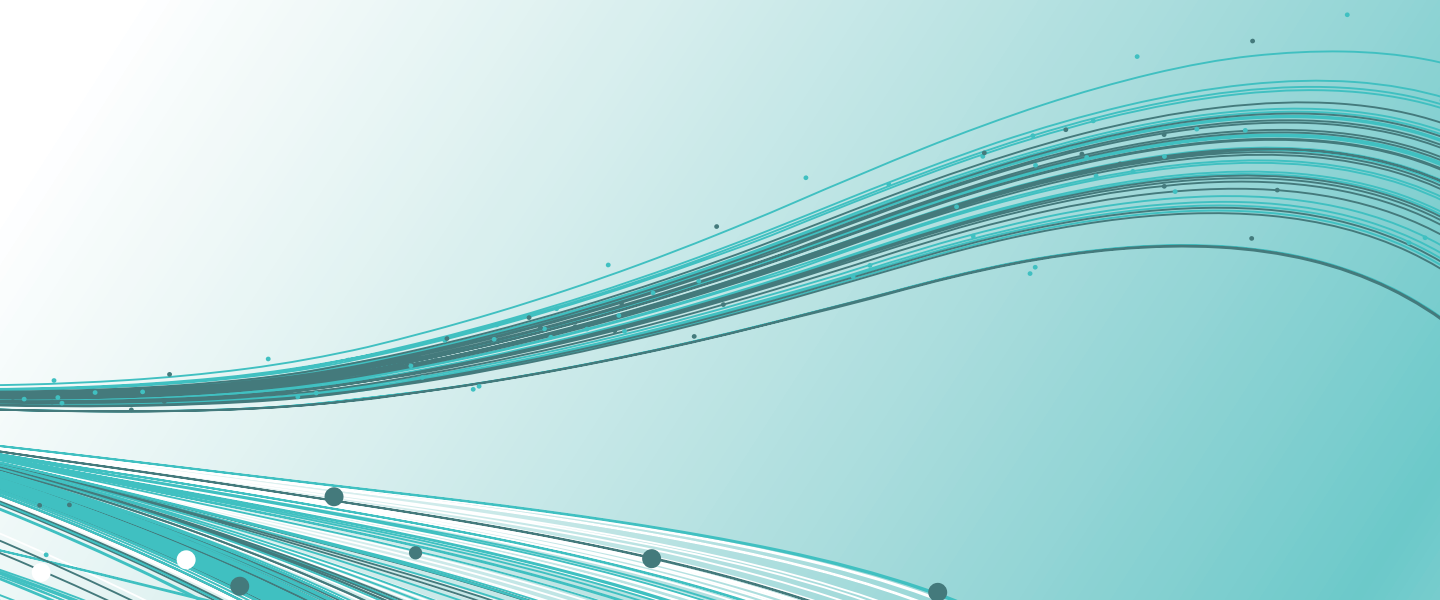
Important things to remember

- When storing, keep the bottle upright and tightly closed between each use and protect from light
- Keep at room temperature between 20°C–25°C
- Opening the bottle:
 - When you open the bottle of RADICAVA® Oral Suspension for the first use, write the date you open the bottle on the bottle label
 - After opening the bottle of RADICAVA® Oral Suspension, use within 15 days
- Once a bottle of RADICAVA® Oral Suspension has been opened and used, a white crust may form on the neck or the side of the bottle. This is due to normal use and you can continue to use as prescribed.
- Throw away any RADICAVA® Oral Suspension that is not used within 15 days after opening the bottle or if the bottle is unopened 30 days from the date of shipment indicated on the carton pharmacy label. Ask your pharmacist how to properly throw away (discard) RADICAVA® Oral Suspension you are no longer able to use.
- Keep RADICAVA® Oral Suspension and all medicines out of reach from children
- Call your doctor for medical advice about any side effects you may be experiencing



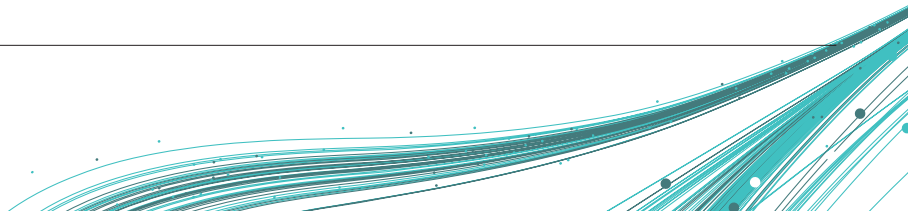
If you want more information about RADICAVA® Oral Suspension

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) or the manufacturer's website www.RADICAVA.ca or by calling 1-888-212-2253



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MTP Patient Support® may help you

If you have any questions, feel free to reach out via:



1-833-211-MTPT (6878)



MTP@innomar-strategies.com

The MTP Patient Support® team is available Monday–Friday, 8 a.m.–8 p.m. EST

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