

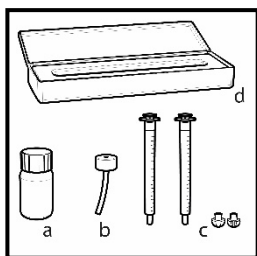
Patient Administration Instructions for Rapamune® Oral Solution

Be sure that you read and understand the following instructions for the correct way to dilute and take Rapamune Oral Solution. Ask your pharmacist or doctor if you are not sure.

Important:

- Always keep the bottle in an upright position.
- You may store Rapamune Oral Solution that is in a syringe at room temperature up to 25°C or in the refrigerator at 2°C to 8°C for up to 24 hours. See “How should I store Rapamune Oral Solution?” at the end of these Instructions for Use.
- Rapamune Oral Solution can develop a slight haze when it is refrigerated. If this happens, bring the Rapamune Oral Solution to room temperature and then gently shake the bottle until the haze goes away. The presence of this haze does not affect the quality of Rapamune Oral Solution.
- Only use a glass or plastic cup to dilute Rapamune Oral Solution.

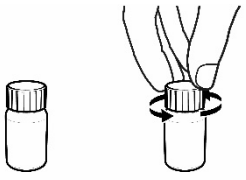

Each Rapamune Oral Solution carton contains:

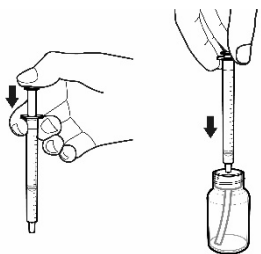
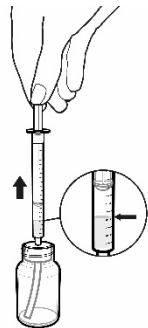
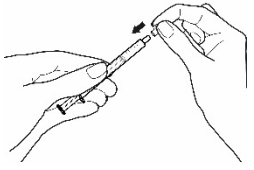
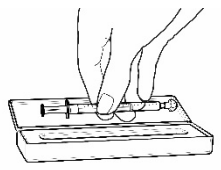
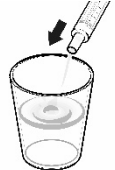


- a) a 60 mL fill amber glass bottle of sirolimus (concentration of 1 mg/mL)
- b) 1 oral syringe adapter for fitting into the neck of the bottle
- c) enough disposable oral syringes (amber colour) and caps for daily dosing
- d) 1 carrying case

You will also need:

- a glass or plastic cup
- 180 mL of water or orange juice only

 <p>Figure 1: Opening the bottle</p>	<p>1. Open the solution bottle.</p> <ul style="list-style-type: none"> • Remove the safety cap by squeezing the tabs on the cap and twisting counterclockwise (Figure 1).
 <p>Figure 2: Inserting adapter</p>	<p>2. The first time you use a bottle of Rapamune Oral Solution.</p> <ul style="list-style-type: none"> • Insert the oral syringe adapter (plastic tube with stopper) tightly into the bottle until it is even with the top of the bottle (Figure 2). • Do not remove the oral syringe adapter from the bottle once inserted.

 <p>Figure 3: Inserting syringe</p>	<p>3. Use a new disposable amber oral syringe for each dose of Rapamune Oral Solution.</p> <ul style="list-style-type: none"> • Fully push down (depress) on the plunger of the disposable amber oral syringe. • Then, tightly insert the oral syringe into the opening in the adapter (Figure 3).
 <p>Figure 4: Withdrawing solution</p>	<p>4. Withdraw the prescribed amount of Rapamune Oral Solution.</p> <ul style="list-style-type: none"> • Gently pull back the plunger of the syringe until the level of the oral solution is even with the mark on the syringe for the prescribed dose. • Always keep the bottle in an upright position. • If bubbles form in the oral solution in the syringe, empty the syringe into the bottle and repeat step 4 (Figure 4). • You may need to repeat Step 4 more than once to deliver your dose.
 <p>Figure 5: Capping syringe</p>  <p>Figure 6: Placing syringe in carrying case</p>	<p>5. If your doctor tells you to carry your medicine with you.</p> <ul style="list-style-type: none"> • Fill the syringe to the prescribed dose and place a cap securely on the syringe. The cap should snap into place (Figure 5). • Place the capped syringe in the enclosed carrying case (Figure 6).
 <p>Figure 7: Emptying syringe into glass</p>	<p>6. Taking a dose of Rapamune Oral Solution.</p> <ul style="list-style-type: none"> • Empty the syringe into a glass or plastic cup containing at least 60 mL (1/4 cup) of water or orange juice, stir vigorously for 1 minute and drink right away (Figure 7). • Refill the container with at least 120 mL (1/2 cup) of water or orange juice, stir vigorously again and drink the rinse solution. • Do not mix Rapamune Oral Solution with grapefruit juice, or other liquids.

	<ul style="list-style-type: none"> • Only glass or plastic cups should be used to mix Rapamune Oral Solution. • The syringe and cap should be used only one time and then thrown away.
	7. Always store the bottles of medication in the refrigerator.

How should I store Rapamune Oral Solution?

- Store bottles of Rapamune Oral Solution in the refrigerator at 2°C to 8°C.
- Protect from light.
- Store Rapamune Oral Solution that is in a syringe at room temperature up to 25°C or in the refrigerator at 2°C to 8°C for up to 24 hours.
- Once a bottle of Rapamune Oral Solution is opened, it should be used within 1 month.
- Use any diluted Rapamune Oral Solution right away.

Keep Rapamune and all medicines out of the reach of children.



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