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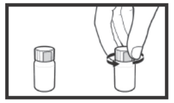
Rapamune®
(sirolimus)
Oral Solution
1 mg/mL

14577200

Instructions for Use for RAPAMUNE® (sirolimus) Oral Solution

1

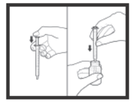


Open the solution bottle. Remove the safety cap by squeezing the tabs on each side of the cap and twisting counterclockwise (Figure 1).

2

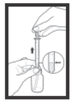
The **first time** you use a bottle of RAPAMUNE Oral Solution: Insert the oral syringe adapter (plastic tube with stopper) tightly into the bottle until it is even with the top of the bottle (Figure 2). Do not remove the oral syringe adapter from the bottle once inserted.

3



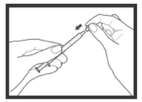
Use a new disposable amber oral syringe for each dose of RAPAMUNE Oral Solution. Fully push down (depress) on the plunger of the disposable amber oral syringe. Then, tightly insert the oral syringe into the opening in the adapter (Figure 3).

4



Withdraw the prescribed amount of RAPAMUNE Oral Solution: Gently pull back the plunger of the syringe until the level of the oral solution is even with the marking on the syringe for your prescribed dose. Always keep the bottle in an upright position. If bubbles form within 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 draw up your prescribed dose.

5



If your doctor tells you to carry your medicine with you: If you need to carry your RAPAMUNE Oral Solution in a filled syringe, place a cap securely on each syringe. The cap should snap into place (Figure 5).

6

Place the capped syringe in the enclosed carrying case (Figure 6). If you need more than 1 carrying case, talk with your doctor or pharmacist.

7

Taking a dose of RAPAMUNE Oral Solution: Choose a clean flat work surface. Place a clean paper towel on the work surface. Wash and dry your hands. Empty the syringe into a glass or plastic cup containing at least 2 ounces (1/4 cup, 60 mL) of water or orange juice, stir vigorously for 1 minute and drink right away (Figure 7). If more than 1 syringe is needed for your prescribed dose, empty the oral solution from each syringe into the same glass or plastic cup of water or orange juice. Refill the container with at least 4 ounces (1/2 cup, 120 mL) of water or orange juice, stir vigorously again and drink the rinse solution. Do not mix RAPAMUNE Oral Solution with apple juice, grapefruit juice, or other liquids. 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. Throw away the paper towel and clean the work surface. Wash your hands.

8

Always store the bottles of medication in the refrigerator.

You may store RAPAMUNE Oral Solution that is in a syringe at room temperature up to 77°F (25°C) or in the refrigerator at 36°F to 46°F (2°C to 8°C) for up to 24 hours. See "How should I store RAPAMUNE?" at the end of Instructions for Use provided in the package insert.

Distributed by
Wyeth Pharmaceuticals LLC
A subsidiary of Pfizer Inc
Philadelphia, PA 19101

Rapamune OS: Made in Canada
Syringe: Made in Denmark

60 mL Patient Kit

Rapamune®
(sirolimus)
Oral Solution
1 mg/mL

DOSAGE AND USE:
See accompanying prescribing information.

Refer to back of box for Instructions for Use for RAPAMUNE (sirolimus) Oral Solution

Keep out of reach of children.

ALWAYS DISPENSE WITH MEDICATION GUIDE

NDC 0008-1030-06

Rapamune®
(sirolimus)
Oral Solution
1 mg/mL

For oral use only.

Each mL of RAPAMUNE contains 1 mg sirolimus.

1.5%-2.5% ethanol

Also contains a mixture of propylene glycol and phosphatidylcholine derived from soy lecithin (and other components) and polysorbate 80.

60 mL Patient Kit

Rx only

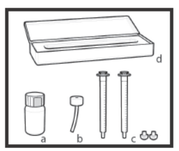
Each RAPAMUNE Oral Solution carton contains:

a) a 2 oz. (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) 30 amber oral syringes and 30 caps for daily dosing
d) 1 carrying case

Also contains: Package Insert and Medication Guide

You will also need:

- glass or plastic cup
- 6 oz. of water or orange juice only



60 mL Patient Kit

Rapamune®
(sirolimus)
Oral Solution
1 mg/mL

Store refrigerated at 2° to 8°C (36° to 46°F).

PROTECT FROM LIGHT

Use contents of bottle within 1 month after opening.

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/s/

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