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NDC 31722-316-31

Usual Dosage: See accompanying prescribing

Refer to side of box for Instructions for Use for

Sirolimus Oral Solution

Keep out of reach of children.

Instructions for Use for Sirolimus Oral Solution Open the solution bottle. Remove the safety cap by squeezing the tabs on each side of the cap and twisting counterclockwise (Figure 1).

bottle (Figure 2).

once inserted.

The **first time** you use a bottle of Sirolimus Oral Solution:

Insert the oral syringe adapter (plastic tube with stopper)

tightly into the bottle until it is even with the top of the

Do not remove the oral syringe adapter from the bottle

each dose of Sirolimus Oral Solution.

the disposable amber oral syringe.

opening in the adapter (Figure 3).

Withdraw the prescribed amount of Sirolimus Oral

Gently pull back the plunger of the syringe until the level

of the oral solution is even with the marking on the

empty the syringe into the bottle and repeat step 4

You may need to repeat step 4 more than once to draw

Always keep the bottle in an upright position. If bubbles form within the oral solution in the syringe,

syringe for your prescribed dose.

up your prescribed dose.

Use a new disposable amber oral syringe for

Fully push down (depress) on the plunger of

Then, tightly insert the oral syringe into the

Each dose of Sirolimus Oral Solution should be placed in an oral syringe. Place a cap securely on each syringe. The cap should snap into place (Figure 5).

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. See Step 8 for storage instru-

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

Taking a dose of Sirolimus Oral Solution:

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 Sirolimus Oral Solution with apple juice, grapefruit juice, or other liquids. Only glass or plastic cups should be used to mix Sirolimus 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.

You may store Sirolimus 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 Sirolimus Oral Solution?" at the end of Instructions for Use provided in the package insert.

 ${\bf 8} \quad \hbox{Always store the bottles of medication in the refrigerator}.$

U.S. Contact Number: 1-866-495-1995

Medication Guide available at http://camberpharma.com/medicationguides.

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Sirolimus Oral Solution

For oral use only.

Each mL of Sirolimus Oral Solution contains 1 mg sirolimus. Each Sirolimus Oral Solution carton contains:

1.5% to 2.5% ethanol

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

PHARMACIST: Dispense the Medication Guide provided separately

60 mL Patient Kit

(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

a) a 2 oz. (60 mL fill) amber glass bottle of sirolimus

PROTECT FROM LIGHT.

Use contents of bottle within 1 month after

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

150 mm

70 mm

150 mm

70 mm

Artwork information			
Customer	Camber	Market	USA
Dimensions	150 x 70 x 140 mm		
Printing Colours	Pantone 1805 C Pantone 2736 C Black		
Non Printing Colors	Die cut Unvarnish Area Perforation		
Pharma Code:	311		
Others:	NA		