

## Instructions for Use

### PROGRAF® Granules (PRO-graf) (tacrolimus for oral suspension)

Your healthcare provider has prescribed PROGRAF® Granules, which comes in individual packets that will need to be mixed with water before giving the medicine to your child.

Read this Instructions for Use and the Patient Information for the first time and each time you get a refill of PROGRAF Granules (tacrolimus for oral suspension). There may be new information.

This Instructions for Use does not take the place of talking to your child's healthcare provider about their medical condition or treatment. Ask the healthcare provider if you have any questions about how to mix or give a dose of PROGRAF Granules the right way.

#### **Important information:**

**These instructions are for preparing PROGRAF Granules only.**

**These instructions should not be used for PROGRAF capsules.**

- Mix PROGRAF Granules in water to make an oral suspension.
- Give all of the prepared oral suspension to your child right away after preparing. **Do not** save the prepared oral suspension for later use.
- **Use glass or metal materials** to prepare your child's dose of PROGRAF Granules.
  - **Do not** use any plastic (PVC) materials to prepare PROGRAF Granules. The granules will stick to a plastic container and your child may not receive their full dose.
- **Do not** breathe in (inhale) or let the granules in PROGRAF or the prepared oral suspension come in contact with your skin or eyes.
  - If you get the granules or the prepared oral suspension on your skin, wash the area well with soap and water.
  - If you get the granules or the prepared oral suspension in your eyes, rinse with plain water.

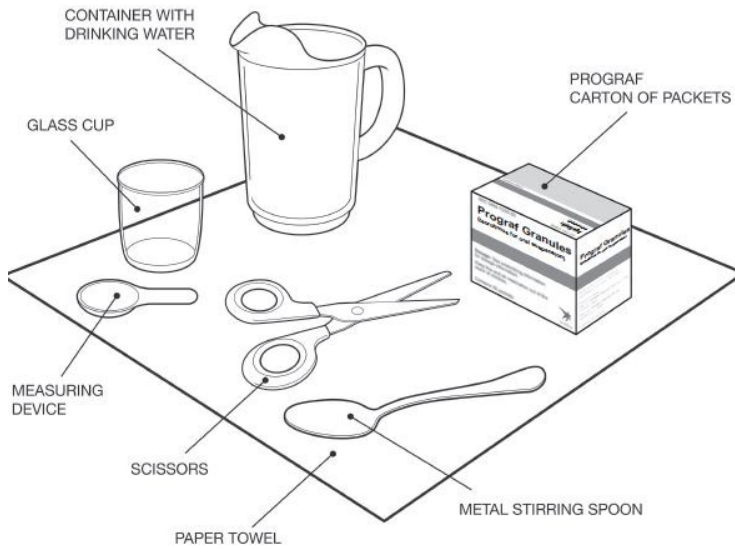
If you spill the granules, wipe the surface with a wet paper towel. If you spill the prepared oral suspension, dry the area with a dry paper towel and then wipe the area with a wet paper towel. Throw away the paper towels in the trash and wash your hands well with soap and water.

**For each dose of PROGRAF Granules mixed with water that will be given using a glass cup,** you will need the following supplies (See Figure A):

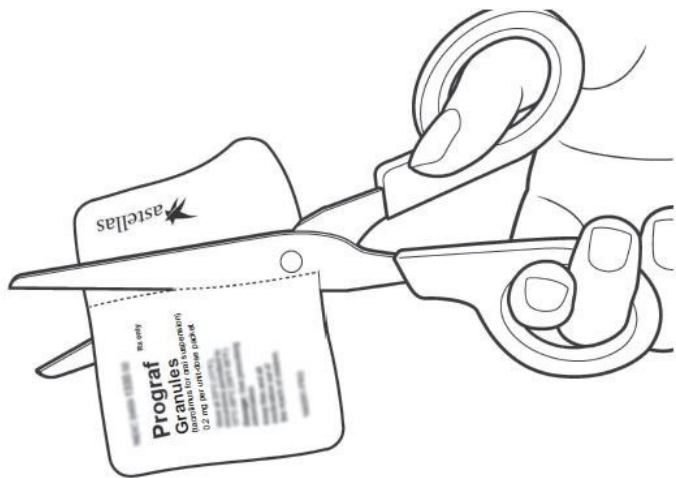

- Carton containing PROGRAF Granules packets. **Follow the instructions on the carton for the number of packets your child's healthcare provider has prescribed for each dose.**
- paper towels
- pair of scissors
- **metal** stirring spoon
- measuring device


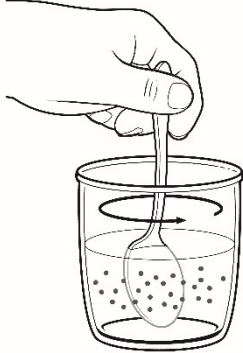

- 1 small clean **glass** cup (plastic containers should not be used)
- container with drinking water

**Figure A**



<b>Step 1</b>	Choose a clean flat work surface. Place a clean paper towel on the work surface. Place the supplies to prepare the dose on the paper towel.	
<b>Step 2</b>	Wash and dry your hands.	
<b>Step 3</b>	Remove the prescribed number of PROGRAF Granules packets from the carton.	<p>A line drawing showing a hand opening a box of PROGRAF Granules. The box is tilted, and the hand is lifting the top flap. The box is labeled 'PROGRAF Granules (tacrolimus for oral suspension)'. Below the main label, there is smaller text: 'NDC 68881-1231-01', 'Use PROGRAF Granules only with water. Do not crush and do not chew. Place the granules in a glass or plastic cup and add water to make a suspension. Do not use if the granules are not in their original packaging. Contains 30 individual packets.' There is also a small logo in the bottom right corner of the box.</p>

<b>Step 4</b>	Using a pair of scissors, cut along the dotted line on 1 PROGRAF Granules packet to open it.	 A line drawing showing a hand holding a pair of scissors, cutting along a dotted line on a small rectangular packet. The packet is labeled 'astellas' and 'Prograf Granules'. The scissors are positioned to cut the top edge of the packet.
<b>Step 5</b>	Empty all of the granules in the packet into the glass cup. Check for any remaining granules in the packet and empty these into the glass cup.	 A line drawing showing a hand holding a small rectangular packet tilted over a glass cup. Small dark dots representing granules are falling from the packet into the cup. The packet is labeled 'Prograf Granules'.
<b>Step 6</b>	If more than 1 packet of PROGRAF Granules is needed for your child's prescribed dose, repeat Steps 4 and 5 using the number of packets needed for the prescribed dose.	

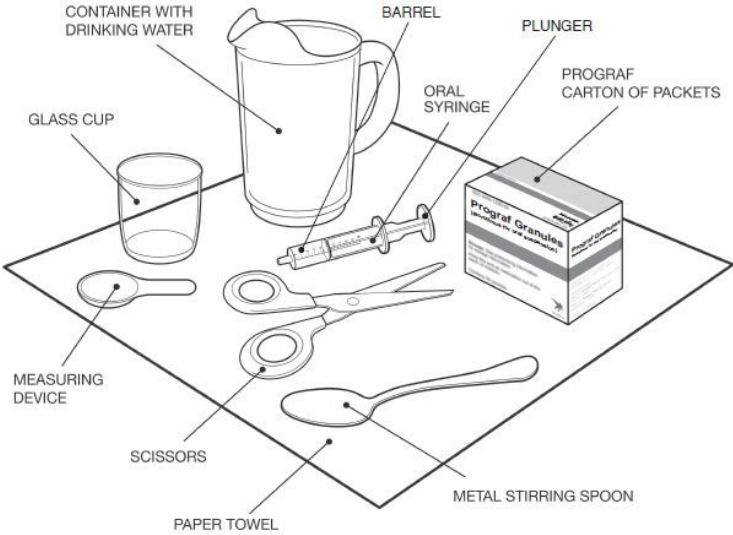
<p><b>Step 7</b></p>	<p>Add 1 to 2 tablespoons (15 to 30 milliliters) of room temperature drinking water to the glass cup containing the granules.</p>	
<p><b>Step 8</b></p>	<p>Gently stir the granules and water in the glass cup with a metal stirring spoon. The granules will not completely dissolve. You will see granules that are suspended in the water.</p>	
<p><b>Step 9</b></p>	<p>Give the granules and water suspension in the glass cup to your child. Make sure your child drinks all of the medicine in the cup. Give all of the medicine to your child right away after preparing. <b>Do not</b> save the medicine for later use.</p>	
<p><b>Step 10</b></p>	<p>To make sure all of the medicine is given to your child, refill the glass cup with the same amount of water used in Step 7.</p>	
<p><b>Step 11</b></p>	<p>Gently swirl the glass cup to mix any remaining granules.</p>	
<p><b>Step 12</b></p>	<p>Give all of the medicine in the cup to the child.</p>	

<b>Step 13</b>	Wash the glass cup. Throw away the paper towel and clean the work surface. Wash your hands.
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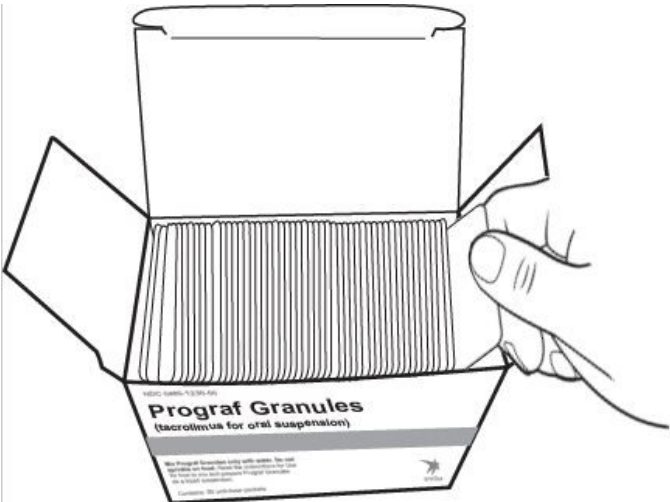
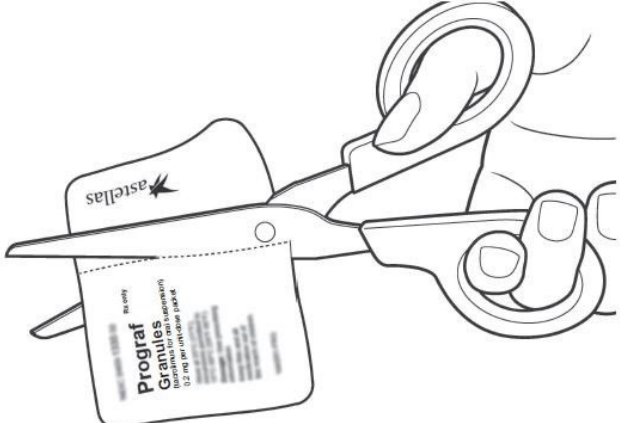

For each dose of **PROGRAF Granules (tacrolimus for oral suspension) mixed with water that will be drawn up and given using an oral syringe**, you will need the following supplies (See Figure B):


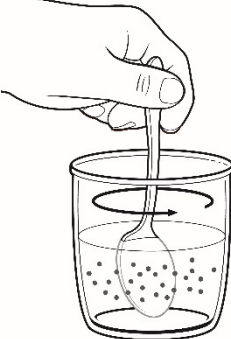
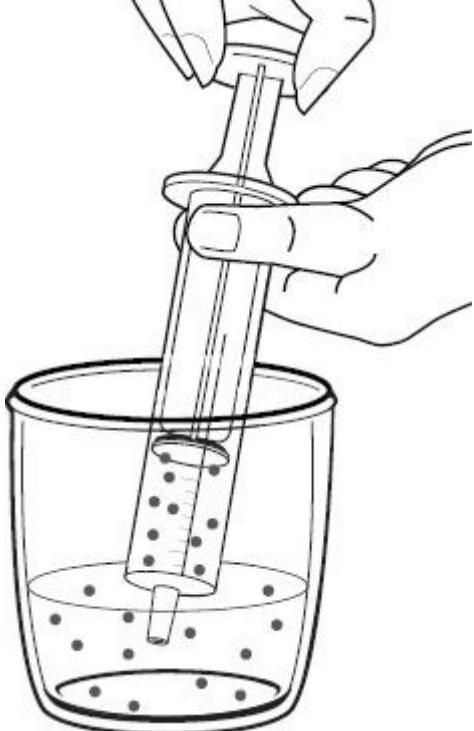
- Carton containing PROGRAF Granules packets. **Follow the instructions on the carton for the number of packets your child’s healthcare provider has prescribed for each dose.**
- paper towels
- pair of scissors
- **metal** stirring spoon
- measuring device
- 1 small clean **glass** cup (plastic containers should not be used)
- container with drinking water
- **1 non-PVC** oral syringe (ask your pharmacist for the oral syringe you should use)


**Figure B**



<b>Step 1</b>	Choose a clean flat work surface. Place a clean paper towel on the work surface. Place the supplies to prepare the dose on the paper towel.	
<b>Step 2</b>	Wash and dry your hands.	

<p><b>Step 3</b></p>	<p>Remove the prescribed number of PROGRAF Granules packets from the carton.</p>	
<p><b>Step 4</b></p>	<p>Using a pair of scissors, cut along the dotted line on 1 PROGRAF Granules packet to open it.</p>	
<p><b>Step 5</b></p>	<p>Empty all of the granules in the packet into the glass cup. Check for any remaining granules in the packet and empty these into the glass cup.</p>	
<p><b>Step 6</b></p>	<p>If more than 1 packet of PROGRAF Granules is needed for your child's</p>	

	prescribed dose, repeat Steps 4 and 5 using the number of packets needed for the prescribed dose.	
<b>Step 7</b>	Add 1 to 2 tablespoons (15 to 30 milliliters) of room temperature drinking water to the glass cup containing the granules.	
<b>Step 8</b>	Gently stir the granules and drinking water in the glass cup with a metal stirring spoon. The granules will not completely dissolve. You will see granules that are suspended in the drinking water.	
<b>Step 9</b>	Insert the tip of the oral syringe into the glass cup. Pull back on the plunger of the oral syringe to draw up the suspension.	

<p><b>Step 10</b></p>	<p>Place the tip of the oral syringe in your child’s mouth along the inner cheek. Slowly push the plunger all the way down to give your child <b>all</b> of the medicine in the oral syringe.</p> <p>Repeat Steps 9 and 10 until the glass cup is empty.</p> <p>Give all of the medicine to your child right away after preparing. <b>Do not</b> save the medicine for later use.</p>	
<p><b>Step 11</b></p>	<p>To make sure all of the medicine is given to your child, refill the glass cup with the same amount of drinking water used in Step 7.</p>	
<p><b>Step 12</b></p>	<p>Gently swirl the glass cup to mix any remaining granules.</p>	
<p><b>Step 13</b></p>	<p>Repeat Steps 9 and 10 until the glass cup is empty.</p>	
<p><b>Step 14</b></p>	<p>Rinse the plunger and barrel of the syringe well with drinking water and dry well before storing the oral syringe.</p>	
<p><b>Step 15</b></p>	<p>Wash the glass cup. Throw away the paper towel and clean the work surface. Wash your hands.</p>	

**How should I store PROGRAF Granules packets?**

Store PROGRAF Granules packets at room temperature between 68°F to 77°F (20°C to 25°C).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

**Keep PROGRAF Granules and all medicine out of the reach of children.**

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Distributed by:

**Astellas Pharma US, Inc.**

Northbrook, IL 60062

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