



Direct Healthcare Provider Communication

April 2024

IMPORTANT USAGE INFORMATION

Subject: Introducing a new universal bottle adapter for Gengraf® Oral Solution (cyclosporine oral solution, USP [MODIFIED])

Dear Healthcare Provider:

The purpose of this letter is to introduce a new universal bottle adapter for Gengraf® Oral Solution (cyclosporine oral solution, USP [MODIFIED]) because the current press-in bottle adapter is no longer manufactured. Due to the inclusion of a new bottle adapter, there are required changes in the product's use.


Because patients will require revised instruction for usage of the new adapter, an "Instructions for Use" (IFU) leaflet will be provided with the product. This IFU leaflet contains information on how to prepare and take a correct dose of Gengraf® Oral Solution and describes the contents of each carton and additional supplies to ensure the proper dose. The IFU leaflet also provides essential information for preparation of Gengraf® Oral Solution and the safe handling and storing of product, bottle adapter, syringe, and bottle.

Healthcare Provider Action

Ensure the patient has access to Gengraf® Oral Solution Instructions for Use (IFU) leaflet and emphasize how important it is for the patient to read the full instructions before taking the drug product.

Counsel patients about the existence and use of the new bottle adapter, specifically:

1	Changes to Gengraf® Oral Solution	<ul style="list-style-type: none">• There are no changes to the drug product and syringe.• A new bottle adapter has been introduced.• A separate stand-alone IFU has been introduced.• The carton labeling has been revised.
2	Retain child-resistant function; the new bottle adapter is different in appearance and is NOT child-resistant .	Do NOT discard the cap after opening. The cap must be used to reseal the bottle to retain child-resistant functionality.
3	Handling and Storage	The bottle adapter is removed after each use and the bottle is resealed with the child-resistant cap for storage between doses.

		
4	<p>Wipe the syringe and bottle adapter with a clean, dry tissue.</p> <p>Do not rinse them.</p>	

Reporting Adverse Events

Healthcare providers and patients are encouraged to report adverse events and medication errors in patients taking Gengraf, to AbbVie at 1-800-633-9110.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm.
- Regular mail or fax: Download a form at www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form. Complete the form and return it to the specified address on the form or submit the form by fax to 800-FDA-0178 (800-332-0178).

Company Contact

If you have any questions about the information contained in this letter or the safe and effective use of Gengraf® Oral Solution, you may contact our Medical Information department at 1-800-633-9110.

This letter is not intended to provide all the details concerning the use of the new adapter for Gengraf® Oral Solution or to give a complete description of the benefits and risks related to the use of Gengraf® Oral Solution. Please refer to the IFU leaflet and the full Prescribing Information including Boxed Warning provided with the product or visit <https://www.rxabbvie.com/pdf/gengraf-oral.pdf>.

For additional information, please call 1-800-633-9110 or visit <https://www.gengraf.com/hcp>.

Sincerely,



Mudra Kapoor
Vice President Specialty & Global Medical Operations
Global Medical Affairs, Research & Development

Enclosure(s): Revised Instructions for Use (IFU).

INSTRUCTIONS FOR USE
GENGRAF® (jen-graf) ORAL SOLUTION
(cyclosporine oral solution, USP [MODIFIED])

This Instructions for Use contains information on how to prepare and take a dose of Gengraf Oral Solution. Read this Instructions for Use before taking Gengraf Oral Solution for the first time, and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical treatment or condition.

Supplies

Each carton contains (see **Figure A**):

- a. 5 mL syringe
- b. 50 mL bottle of Gengraf Oral Solution
- c. Bottle adapter
 - The bottle adapter is not child-resistant.

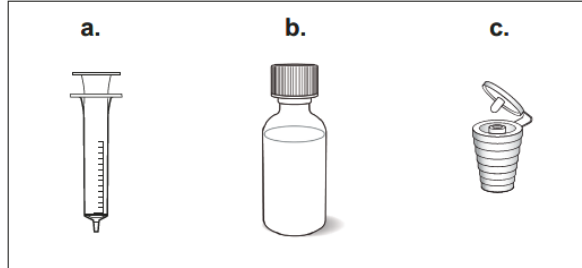


Figure A


You will also need:

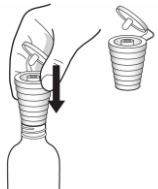
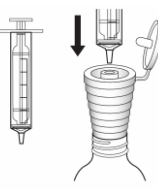
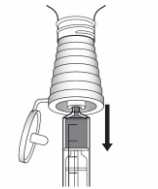
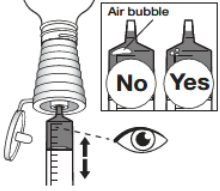
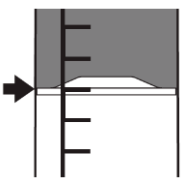


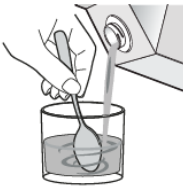
- Glass cup
- Room-temperature orange or apple juice
- Clean towel or tissue



Important Information You Need to Know Before Taking Gengraf Oral Solution

- Do not use if the tamper-evident tape on the carton top or bottom is broken or missing before your first dose.
- Do not use if the product is expired.
- Do not rinse the **syringe** before use. If water gets into the product through the syringe, it will cause variation in dose.
- Do not rinse the **bottle adapter** before use. If water gets into the product through the bottle adapter, it will cause variation in dose.
- Always use the provided syringe for accurate dosing with less waste.
- **Do not** dilute with milk or grapefruit juice.
- Diluting with orange or apple juice improves taste. Do not frequently change the type of juice used.
- Make sure the juice is at room temperature.

Preparing and Taking the Gengraf Oral Solution Dose:

1		<p>To open the Gengraf Oral Solution bottle, push down on the child-resistant cap and turn it.</p> <ul style="list-style-type: none">• Do not discard the child-resistant cap.
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2		<p>Push the bottle adapter into the bottle until it feels tight and secure. Part of the bottle adapter will remain above the bottle rim.</p> <ul style="list-style-type: none"> • Do not rinse the bottle adapter before use.
3		<p>Open the cover on top of the bottle adapter if it is closed. Insert the tip of the syringe firmly into the opening of the bottle adapter.</p> <ul style="list-style-type: none"> • Do not rinse the syringe before use.
4		<p>Invert the bottle. Draw up the prescribed amount of Gengraf Oral Solution with the syringe.</p>
5		<p>Remove large bubbles from the syringe.</p> <ul style="list-style-type: none"> • With the syringe attached to the bottle, move the plunger up and down to return air bubbles back into the bottle.
6		<p>After any large air bubbles are removed, hold the syringe at eye level and adjust the plunger until the edge of the plunger is even with the marking of the dose, as pictured.</p>
7		<p>Turn the bottle upright, then detach the syringe. Transfer the full prescribed dose of Gengraf Oral Solution from the syringe into a glass cup containing at least a few ounces of room temperature orange or apple juice, and stir.</p> <ul style="list-style-type: none"> • Do not use a plastic cup. • Do not use milk or grapefruit juice. • If the syringe is not large enough to draw up the full prescribed amount, repeat steps 3 through 6 until the full amount has been measured.
8		<p>Once the full dose is mixed in the glass, drink it right away.</p> <ul style="list-style-type: none"> • Do not allow the diluted oral solution to stand before drinking it.
9		<p>After you finish drinking:</p> <ul style="list-style-type: none"> • There will still be Gengraf Oral Solution left inside the glass, even if you cannot see it. • To make sure you get your full dose, pour at least a few ounces of additional juice into the glass, stir, and drink.

10		<p>After use, set the bottle on a flat surface, and grasp the body of the bottle adapter. Twist and pull the adapter to remove it from the bottle.</p> <ul style="list-style-type: none"> • The bottle adapter is not child resistant.
11		<p>Reseal the bottle with the child-resistant cap.</p>
12	<ul style="list-style-type: none"> • Wipe the syringe and bottle adapter with clean, dry tissue. • Do not rinse them. If water gets into the product, it will cause variation in dose. 	
13	<p>Store the syringe and bottle adapter in a clean, dry location.</p>	

Storing Gengraf Oral Solution

- Store Gengraf Oral Solution in the original bottle at room temperature 68°F to 77°F (20°C to 25°C).
- After the bottle is opened for first use, the contents must be used within 2 months.
- Keep Gengraf Oral Solution and all medicines out of the reach of children.

Call your healthcare provider or 1-800-633-9110 if you need help or have any questions about how to take Gengraf Oral Solution.

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AbbVie Inc., North Chicago, IL 60064, U.S.A.

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

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