

INSTRUCTIONS FOR USE
VIGAFYDE™ (VIG-uh-fide)
vigabatrin oral solution

Read this Instructions for Use before your baby starts taking VIGAFYDE and each time you get a refill. There may be new information. This information does not take the place of talking with your baby's healthcare provider about your baby's medical condition or treatment. Talk to your baby's healthcare provider if you have any questions about the right dose of medicine to give your baby or how to measure it.

Powder Formulation Users



VIGAFYDE contains more vigabatrin, 100 mg per milliliter (mL) **compared to** other types (formulations) of vigabatrin prepared from powder, at 50 mg per mL.

If your baby is switching from vigabatrin prepared from powder to VIGAFYDE oral solution, your baby's healthcare provider may have prescribed a smaller volume (mL) of medicine than before.

Important Note:

- VIGAFYDE is a concentrated solution compared to other vigabatrin types. Each mL of VIGAFYDE contains 100 mg of vigabatrin.

Each VIGAFYDE oral solution carton contains (see Figure A):

- 1 bottle of VIGAFYDE oral solution
- 1 Medication Guide (not pictured)
- 1 Instructions for Use leaflet (not pictured)



Figure A

The pharmacy will provide (see Figure B) an:

- Oral Syringe
- Bottle Adapter

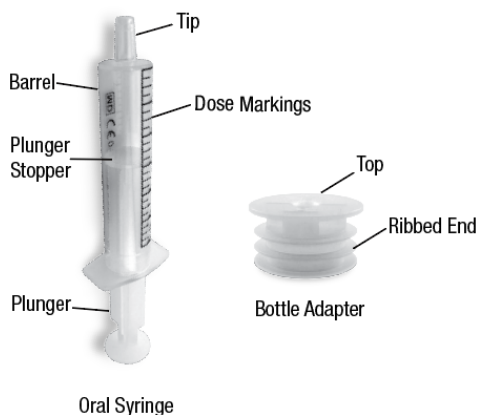


Figure B

- Your baby's healthcare provider will tell you how many milliliters (mL) of VIGAFYDE you will need for each dose.
- Use the oral syringe provided by the pharmacy to measure and give the prescribed dose. Do not use a household teaspoon or tablespoon.
- Stop using other products that contain vigabatrin. Check with your healthcare provider.
- Check the label on the bottle and make sure the expiration date (EXP) has not passed. If the expiration date has passed, **do not** use VIGAFYDE. Contact your pharmacy or healthcare provider to get a new bottle of VIGAFYDE.

How to prepare the bottle for first time use of VIGAFYDE oral solution:

Step 1: If needed, separate the bottle adapter from the oral syringe (see Figure C).

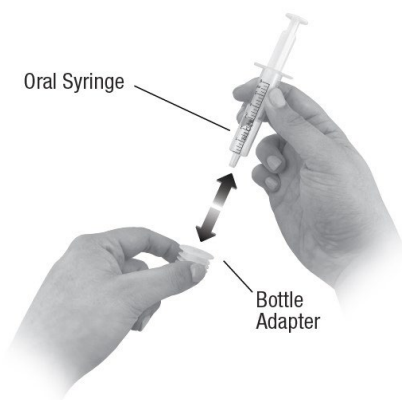


Figure C

Step 2: Remove the child-resistant-cap by pressing down on the cap and turning it counterclockwise (to the left) (see Figure D). Do not throw away the child-resistant cap.



Figure D

Step 3: Completely remove the inner seal from the bottle and throw it away in the household trash. If needed, the tip of the syringe may be used to puncture the inner seal (see Figure E).



Figure E

Inserting the bottle adapter into the VIGAFYDE bottle:

Step 4: Insert the bottle adapter. While holding the bottle firmly on a flat surface, push the ribbed end of the bottle adapter all the way into the neck of the bottle. Make sure that the bottle adapter is fully inserted (see Figure F). Do not remove the bottle adapter from the bottle after it is inserted.



Figure F

Step 5: Put the child-resistant cap back on the bottle by turning it clockwise (to the right). Record the date of opening on the bottle's label. VIGAFYDE may be used for up to 90 days after first opening (see Figure G).



Figure G

How to prepare a dose of VIGAFYDE oral solution:

Step 6: Open the bottle of VIGAFYDE by pressing down on the cap and turning it counterclockwise (to the left) (See Figure D).

Step 7: Use the oral syringe to draw up the total number of mLs of medicine that your baby's healthcare provider tells you to give.

Push the plunger of the oral syringe all the way up towards the tip of the oral syringe to remove air in the oral syringe (see Figure H).

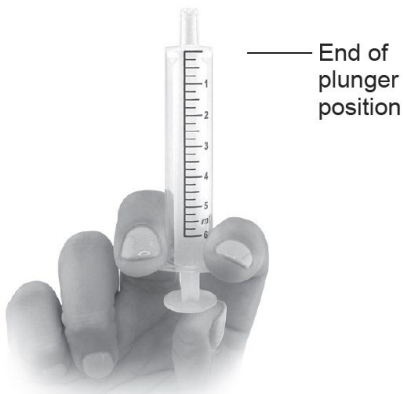


Figure H

Step 8: Place the VIGAFYDE bottle on a flat surface. While keeping the bottle in an upright position, insert the tip of the oral syringe into the opening of the bottle adapter and push down gently (see Figure I).

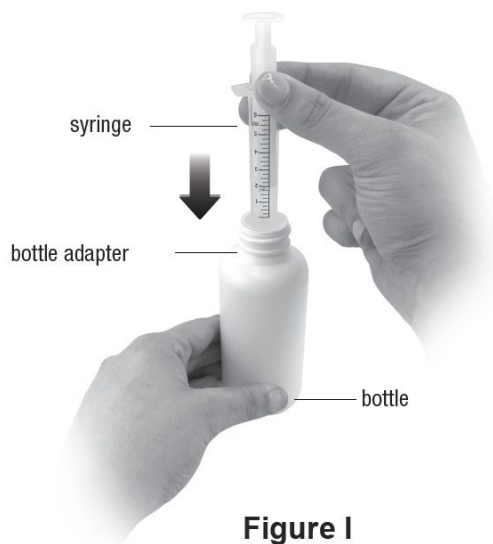


Figure I

Step 9: While holding the oral syringe firmly into the bottle, turn the bottle upside down. Slowly pull back the plunger of the oral syringe until the top of the plunger stopper lines up with the mL marking (dose markings) on the barrel of the oral syringe that matches the number of mLs of medicine your baby's healthcare provider told you to give (see Figure J).

After the prescribed dose is withdrawn, hold the plunger in place to keep the plunger from moving.

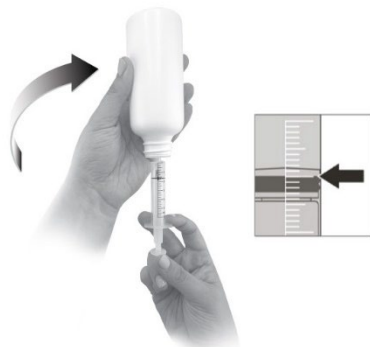


Figure J

How to remove large air bubbles and measure to the prescribed dose:

Step 10: With the oral syringe attached to the bottle, check for air bubbles. Tiny air bubbles are normal. If large air bubbles are present (see Figure K), slowly push up on the plunger until the bubbles are removed. Then slowly pull back on the plunger to measure the prescribed dose. The top of the plunger stopper must line up with the mL markings (dose markings) on the oral syringe for the prescribed dose.

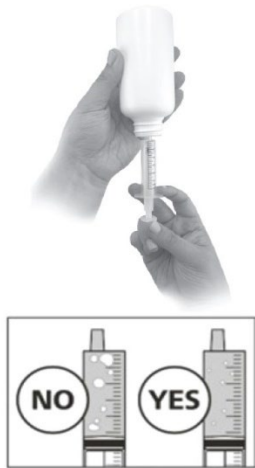


Figure K

Step 11: Continue to hold the plunger in place to keep the plunger from moving. Leave the oral syringe in the bottle adapter and turn the bottle to an upright position. Place the bottle onto a flat surface. Carefully remove the oral syringe from the bottle adapter by gently pulling straight up on the oral syringe while holding the plunger in place (See Figure L).

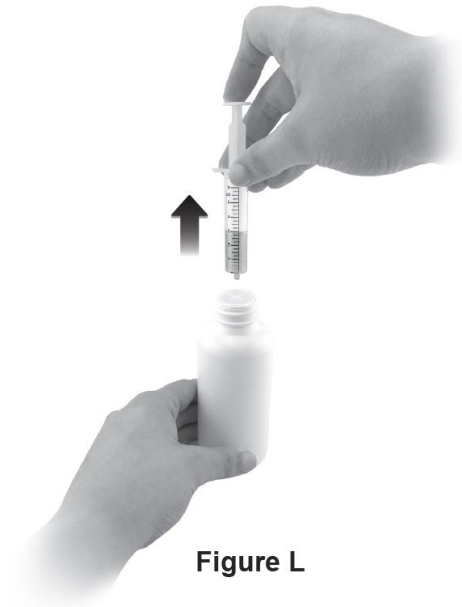


Figure L

Check to make sure that the dose in the oral syringe is the prescribed dose. If the dose of VIGAFYDE is not the right dose, insert the oral syringe tip firmly into the bottle adapter while the bottle is in an upright position. Push the plunger all the way down so that VIGAFYDE flows back into the bottle and repeat Steps 9 through 11.

How to give a dose of VIGAFYDE oral solution:

Step 12: Sit your baby upright when giving a dose of VIGAFYDE. Place the tip of the oral syringe into your baby's mouth and point the oral syringe towards either cheek (see Figure M). Push on the plunger slowly, a small amount at a time, until all the medicine in the oral syringe is given.



Figure M

If the dose you are giving your baby is more medicine than will fit into the syringe provided by the pharmacy, repeat steps 8 to 12 until you give the total dose of medicine prescribed by your healthcare provider.

Step 13: Leave the bottle adapter in place. Put the child-resistant cap back on the bottle by turning it clockwise (to the right). See Figure N.



Figure N

How to clean the oral syringe after use:

Step 14: Rinse the oral syringe with warm water. To clean the oral syringe, remove the plunger by gently pulling it straight out of the barrel of the oral syringe. The barrel and plunger can be rinsed with water, and allowed to air dry. After the oral syringe barrel and plunger are dry, put the plunger back into the oral syringe barrel and store the oral syringe with your medicine.

How should I store VIGAFYDE?

- Store unopened bottles at room temperature between 68°F to 77°F (20°C to 25°C). Once opened, store bottle in a refrigerator or at room temperature between 36°F to 86°F (2°C to 30°C).
- Throw away (discard) any opened bottle of VIGAFYDE 90 days after first opening, even if there is still medicine in the bottle.
- **Keep VIGAFYDE and all medicines out of the reach of children.**

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

Made in the United Kingdom

Manufactured for:

PYROS™

Pyros Pharmaceuticals, Inc.

Parsippany, NJ 07054 U.S.A.

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