

INSTRUCTIONS FOR USE
VYALEV™ [vye-uh-lev]
(foscarbidopa and foslevodopa)
injection, for subcutaneous use

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

Before using VYALEV:

- Only use VYALEV by yourself after you have been shown the right way to use VYALEV and the delivery system (see the Patient Instructions for Use of VYAFUSER Pump).
- Call your healthcare provider or call (866) 4-VYALEV or (866) 489-2538 for help or go to www.VYALEV.com.

How should I store VYALEV?

- Keep the vials in the outer carton to protect the vials from breaking.
- Store VYALEV in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Record the date when VYALEV is first removed from the refrigerator in the space provided on the carton.
- VYALEV may be stored at room temperature up to a maximum of 86°F (30°C) for a single period of up to 28 days.
- After VYALEV has been stored at room temperature, do not return the medicine to the refrigerator.
- If stored at room temperature, throw away (dispose of) VYALEV if not used within 28-days.
- Do not freeze.
- Do not shake.
- If VYALEV is stored in the refrigerator, take one VYALEV vial out of the carton and out of the refrigerator 30 minutes before use. Use the VYALEV at room temperature or you may not get the right amount of the medicine.

Keep VYALEV and all medicines out of the reach of children.

Important Information:

Solution

- **The VYALEV solution color may have changes in color and does not affect how well the medicine works.** It may be colorless, or may have different colors anywhere between light yellow and brown, possibly with purple or red tint. It also may become darker while in the syringe.
- If refrigerated before use, remove the solution vial from refrigerated storage and allow to sit at room temperature out of direct sunlight for 30 minutes.
- **Do not** add any other liquid (dilute) the VYALEV solution or fill the syringe with anything other than what your healthcare provider prescribed.
- **Do not** use VYALEV if the **expiration date (EXP:)** shown on the carton and vial has passed.

Disposable Parts (Vial Adapter and Syringe)

- A new vial adapter must be used with each new vial of VYALEV.
- **Do not** use the VYALEV solution if it has been in the syringe for more than 24 hours.

A. Transfer VYALEV from Solution Vial to Syringe

1. Make sure your work space is clean.

Note: This will help to avoid contamination.

2. Gather supplies, including (see Figure A):

- Solution vial
- Syringe (not included in VYALEV carton)
- Vial adapter (not included in VYALEV carton)
- Alcohol pads (not included in VYALEV carton)

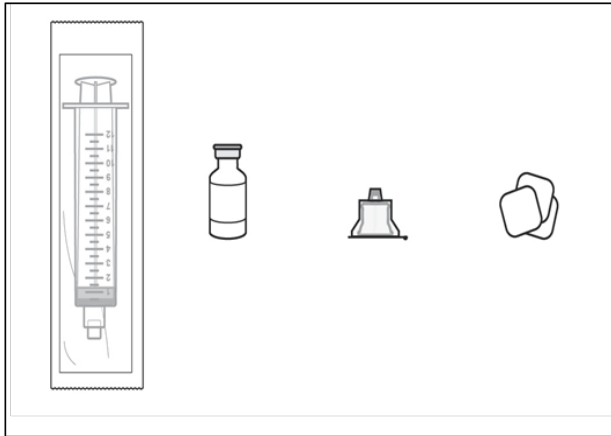


Figure A

Syringe Solution Vial Vial Adapter Alcohol Pads

3. Check over the parts for expiration and for any packaging damage. This should include:

- Solution vial (see Figure B)
- Vial adapter
- Syringe
- Check if the solution is the VYALEV solution prescribed by your healthcare provider.
- **Do not** use the VYALEV solution, vial adapter, or syringe if it is expired.
- **Do not** use any parts if their sterile packaging has been damaged before use.

Note: The product packaging for the infusion set, vial adapter, and syringe show that they are sterile and how they were sterilized.

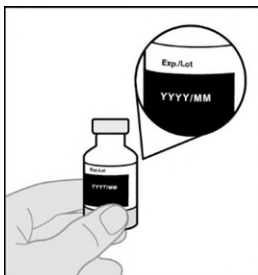


Figure B

4. Check over the contents of the VYALEV vial (see Figure C). Check the following:

- No cloudiness of the liquid.

- No particles seen in the liquid.

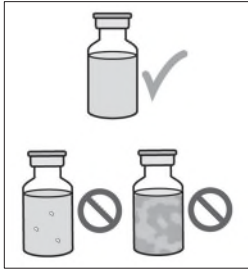


Figure C

- **Do not** use if the VYALEV solution is cloudy or contains flakes or particles.

Note: If refrigerated before use, remove the VYALEV solution vial from refrigerated storage and allow to sit at room temperature, out of direct sunlight, for 30 minutes.

- If refrigerated, **do not** warm VYALEV (in solution vial or syringe) in any way other than letting it warm at room temperature. For example, **do not** warm in a microwave or in hot water.

5. Wash your hands with soap and water and dry them (see Figure D).



Figure D

6. Prepare VYALEV solution vial.

- a. Remove the vial cap (see Figure E).



Figure E

- b. Wipe the top of the solution vial with an alcohol pad and allow to dry (see Figure F).

Note: This will help to avoid contamination.



Figure F

7. Attach the vial adapter to the solution vial.

Read your **Vial Adapter Instructions for Use** for detailed steps.



Vial Adapter

8. Prepare the syringe.

- To decrease the risk of infections, **do not** let the tip of any disposable parts come into contact with any unclean surfaces. If the tip of the vial adapter or syringe comes into contact with an unclean surface, throw (discard) it away and get a new one.
 - a. Get a new syringe and remove it from its packaging.
 - b. Push up on the rubber plunger to fully push out all air (see Figure G).

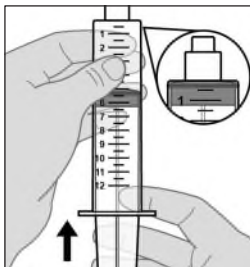


Figure G

9. While holding the vial adapter firmly, attach the syringe to the vial adapter by pushing and then screwing it into place (see Figure H).

- **Do not** overtighten.

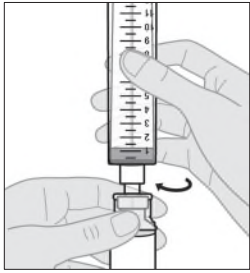


Figure H

- 10. Hold the syringe pointing straight up (vertically) with the solution vial above the syringe (see Figure I).**

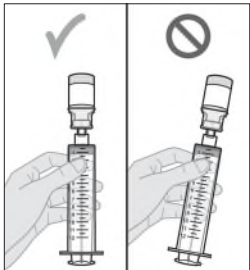


Figure I

- 11. Withdraw all of the medicine from the vial into the syringe.**

- While holding the syringe firmly in one hand, pull down the plunger rod with the other hand to withdraw all of the medicine in the solution vial into the syringe to around the 12 mL mark, or until you see air at the tip of the syringe (see Figure J).

Note: It is important to hold the syringe pointing straight up.

Note: Always withdraw all of the medicine in the solution vial into the syringe.

Note: You will see air (head space) at the tip of the syringe.

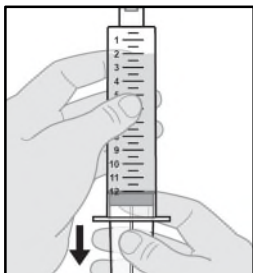


Figure J

- 12. Check for air bubbles.**

- If there are large air bubbles, they must be removed. Air may affect if you get the right amount of medicine (your dose).
 - As seen in Figure K, small bubbles are okay and the air at the tip of the syringe (the head space) is expected.
 - As seen in Figure L, larger air bubbles are not okay. While the air at the top of the syringe (the head space) is expected, the larger bubbles are not.
- a. **If you see large air bubbles**, continue with **Section B: Manually Remove Air Bubbles**.
 - b. **If you see small air bubbles or do not see any air bubbles**, skip the next section and go to **Section C: Remove (Purge) Air from Syringe**.

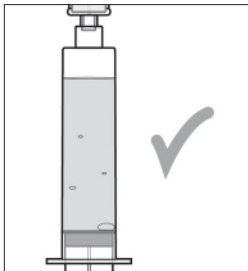


Figure K

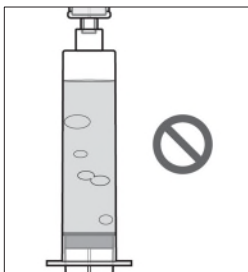


Figure L

B. Manually Remove Air Bubbles

13. Bring the bubbles together into a single air bubble.

- a. Slowly and gently rotate the syringe and tilt it back and forth (see Figure M).
 - **Do not** shake or tap the syringe to remove the air bubbles.

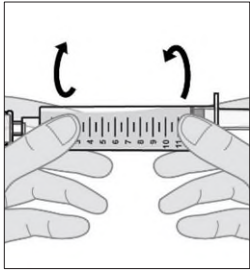


Figure M

Note: If there are still air bubbles, bring the bubbles together by gently rotating the syringe end over end (see Figure N).

- b. When the large air bubbles are brought together into a single air bubble, continue with the next step.

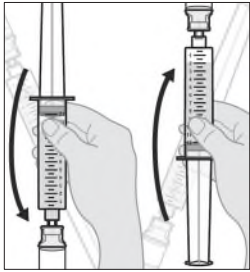


Figure N

C. Remove (Purge) Air from Syringe

14. Push air out of the syringe.

- a. With the solution vial still attached, point the syringe upward.
- b. Slowly push the air out of the syringe and into the vial (see Figure O).
- c. Continue pushing until all of the air is pushed out the syringe and into the solution vial and you can see that there is solution in the syringe tip.

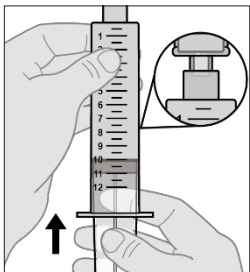


Figure O

Note: Some resistance will be felt as the air is pushed back into the solution vial.

Note: If the syringe is tilted slightly and not pointing straight up, you may see a small air bubble in the corner (see Figure P). This is okay.

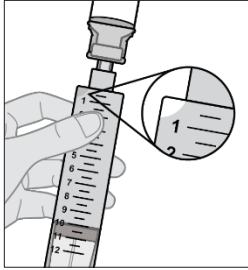


Figure P

15. Turn the syringe and solution vial upside down (invert) so that the solution vial is upright on the table (see Figure Q).

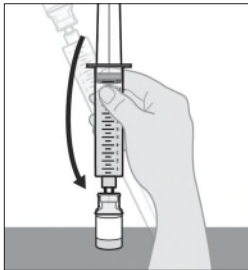


Figure Q

16. Disconnect the syringe from the vial adapter.

- a. Hold the vial adapter firmly with one hand and the barrel of the syringe with the other.
- b. Unscrew the syringe from the vial adapter (see Figure R).

Note: When disconnecting the syringe from the Vial, **do not** push the plunger or else the solution will leak.

- c. Place the syringe on a clean surface, making sure the syringe tip does not contact an unclean surface.
- To decrease the risk of infections, **do not** let the tip of any disposable part come into contact with any unclean surfaces. If the tip of the vial adapter or syringe comes into contact with an unclean surface, throw it away (discard) and get a new one.

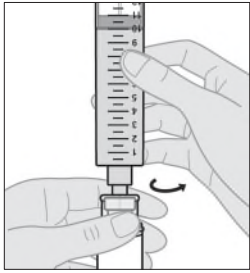


Figure R

- 17. Your syringe is now ready for use. Refer to your pump manual (Patient Instructions for Use of VYAFUSER Pump) for the next steps.**



Patient Instructions for Use of VYAFUSER Pump

D. Disposing of VYALEV

- 18. Used solution vials with the vial adapters still attached should be thrown away (disposed of) in accordance with local regulations or as directed by your healthcare provider.**

This Instructions for Use for VYALEV (foscarnidopa and foslevodopa) is to be used with the VYAFUSER pump (see the Patient Instructions for Use of VYAFUSER Pump).

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