

**Medication Guide**  
**VYALEV™ (vye-uh-lev)**  
**(foscarbidopa and foslevodopa)**  
**injection, for subcutaneous use**

**What is the most important information I should know about VYALEV?**

**VYALEV may cause serious side effects, including:**

- Falling asleep during activities of daily living and somnolence
- Hallucinations/psychosis, or confusion
- Impulse control, compulsive behaviors
- Infusion site reactions and infections
- Cardiovascular ischemic events

Some of these problems may require discussion with your healthcare provider.

See **“What are the possible side effects of VYALEV?”** for more information about side effects.

**What is VYALEV?**

VYALEV is a prescription medicine used for treatment of advanced Parkinson’s disease in adults.

VYALEV contains two medicines, foscarbidopa and foslevodopa.

It is not known if VYALEV is safe and effective in children.

**Do not use VYALEV if you:**

- take a medicine called a nonselective monoamine oxidase (MAO) inhibitor or have taken a nonselective MAO inhibitor within the last 14 days.

Ask your healthcare provider or pharmacist if you are not sure if you take an MAO inhibitor.

**Before using VYALEV, tell your healthcare provider about all your medical conditions, including if you:**

- feel sleepy or have fallen asleep suddenly during the day.
- have or have been seeing things that are not there, hearing sounds or feeling sensations that are not real (hallucinations)
- have or have had unusual urges such as problems with gambling, compulsive eating, compulsive shopping, and increased sex drive.
- have trouble controlling your muscles (dyskinesia).
- have eye problems that cause increased pressure in your eye (glaucoma).
- drink alcohol. Alcohol can increase the chance that VYALEV will make you feel sleepy or fall asleep when you should be awake.
- have or have had heart problems, an abnormal heart rate or have had a heart attack in the past.
- have or have had high blood pressure (hypertension).
- are pregnant or plan to become pregnant. It is not known if VYALEV can harm your unborn baby.
- are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the best way to feed your baby if you take VYALEV.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using VYALEV with certain other medicines may affect each other and cause serious side effects.

**Especially tell your healthcare provider if you take:**

- medicines used to treat high blood pressure (hypertension)
- medicines used to treat depression called nonselective monoamine oxidase (MAO) inhibitor or have taken one within the last 14 days
- dopamine D2 receptor antagonists (antipsychotics or metoclopramide), and isoniazid

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

**How should I use VYALEV?**

- **See the detailed “Instructions for Use of VYALEV” that comes with VYALEV for information on how to prepare syringes of VYALEV for use in the pump, and how to properly throw away (dispose of) used syringes.**

- **See the detailed “Patient Instructions for Use of VYAFUSER Pump” that comes with your pump for complete instructions on how to use the delivery system.**
- Use VYALEV exactly as your healthcare provider tells you to use it.
- Only use VYALEV by yourself after you have been shown the right way to use VYALEV. Ask your healthcare provider if you have any questions.
- Your prescribed dose of VYALEV will be programmed into your pump by a healthcare provider and should only be changed by your healthcare provider.
- Do not stop using VYALEV unless you are told to do so by your healthcare provider.
- Talk with your healthcare provider about what to do in case you are unable to use VYALEV infusion.
- Keep a supply of backup oral Parkinson’s disease medicines that contain levodopa and carbidopa with you at all times.
- VYALEV is given continuously over 24 hours under the skin by a pump.
- VYALEV can be stopped for brief periods of time, such as when taking a shower or short medical procedure. Make sure to change your infusion set (tubing and cannula) and rotate to a different infusion site if you stop the infusion for longer than 1 hour.
- If VYALEV has been stopped for less than 1 hour you will not need a new infusion set (tubing and cannula) and you will not need to rotate to a different infusion site.
- If your infusions have been stopped for longer than 3 hours, consider also giving yourself a loading dose to quickly get your symptoms back under control.
- Have oral carbidopa and levodopa available in case your treatment with VYALEV is stopped for 1 hour or longer.
- You may call 866-4-VYALEV (866-489-2538) for additional help or go to [www.vyalev.com](http://www.vyalev.com).

**What should I avoid while using VYALEV?**

- **Do not** drive, operate machinery, or do other activities until you know how VYALEV affects you. Sleepiness and falling asleep suddenly caused by VYALEV can happen as late as 1 year after you start your treatment.

**What are the possible side effects of VYALEV?**

- **See “What is the most important information I should know about VYALEV?”**

**VYALEV can cause serious side effects including:**

- **Seeing things that are not there, hearing sounds or feeling sensations that are not real (hallucinations). This is a common and sometimes serious side effect.** Hallucinations can happen in people who use VYALEV. Tell your healthcare provider if you have hallucinations.
- **Unusual urges.** Some people taking certain medicines to treat Parkinson’s disease, including VYALEV, have reported problems, such as gambling, compulsive eating, compulsive shopping, and increased sex drive.  
If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.
- **Infusion site reactions and infections. This is a common and sometimes serious side effect .** Some people using VYALEV have had reactions and infections at the infusion site. Remove your cannula and **call your healthcare provider if you have any of the following symptoms of an infection.**
  - local spreading of redness
  - swelling
  - change in color when pressing on the area
  - pain
  - warmth
  - fever
- To prevent infection, clean your infusion site the way your healthcare provider has shown you (aseptic technique) and change your infusion site at least every 3 days using a new infusion site that is at least 1 inch from a site you used in the last 12 days.
- **Withdrawal-emergent fever (hyperpyrexia) and confusion.** Call your healthcare provider if you have any of the following symptoms after stopping VYALEV:
  - fever
  - confusion
  - severe muscle stiffness

- **Uncontrolled sudden movements (dyskinesia). This is a common and sometimes serious side effect.** If you have new dyskinesia, or your dyskinesia gets worse, tell your healthcare provider. This may be a sign that your dose of VYALEV or other medicines to control your Parkinson's disease may need to be adjusted.
- **Heart attack or other heart problems.** Tell your healthcare provider if you have had increased blood pressure, a fast or irregular heartbeat or chest pain.
- **Worsening of the increased pressure in your eye (glaucoma).** The pressure in your eyes should be checked after starting VYALEV.

**Tell your healthcare provider or get medical care right away if you have any of the above symptoms. Your healthcare provider will tell you if you should stop treatment with VYALEV and if needed, tell you how to discontinue VYALEV.**

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of VYALEV. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **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.**

#### **General information about the safe and effective use of VYALEV**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VYALEV for a condition for which it was not prescribed. Do not give VYALEV to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about VYALEV that is written for healthcare professionals.

#### **What are the ingredients in VYALEV?**

**Active ingredients:** foscarnidopa and foslevodopa

**Inactive ingredients:** Sterile water for injection. Sodium hydroxide and hydrochloric acid may be used to adjust the pH to 7.4.

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

©2024 AbbVie. All rights reserved.

VYALEV and its design are trademarks of AbbVie AB.

For more information, call 1-866-4-VYALEV (1-866-489-2538) or go to [www.VYALEV.com](http://www.VYALEV.com).