



VYALEV[®]
foscarbidopa/foslevodopa
Injection for subcutaneous use
12 mg/240 mg per mL

For the treatment of motor
fluctuations in adults with
advanced Parkinson's disease



VYALEV User Guide for Healthcare Professionals

**24-hour continuous treatment for your patients
with Parkinson's disease¹**

SAFETY CONSIDERATIONS

VYALEV is **contraindicated** in patients who currently take or have taken (within 2 weeks) a nonselective monoamine oxidase (MAO) inhibitor, as concurrent use can cause hypertension.

Please see additional Important Safety Information throughout.
Please see accompanying full [Prescribing information](#).





Supplies and system components



Replaced at least once per day^{1,2}



Medication vial



Vial adapter



Syringe



Rechargeable battery

Replaced at least once every 3 days^{1*}



Tubing



Cannula insertion device with cannula

*The infusion set may look different from the one shown here.
Please see System Component Instructions for Use at <https://www.devices.abbvie.com>.
Please see Battery Charger and HCP Pump Instructions for Use at <https://www.rxabbvie.com>.

SAFETY CONSIDERATIONS (cont'd)

VYALEV may cause **sudden falling asleep** during daily activities and somnolence; **hallucinations/psychosis**; compulsive behavior or **lack of impulse control**; **infusion site reactions and infections**; **withdrawal-emergent hyperpyrexia** and confusion; **dyskinesia**; **vitamin B6 deficiency** and **seizures**; **cardiovascular ischemic events**; or worsening **glaucoma**.

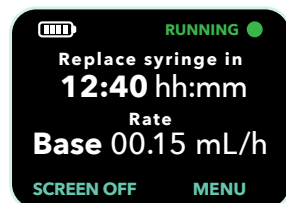
Please see additional Important Safety Information throughout. Please see accompanying Full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

Continuous 24-hour dosing

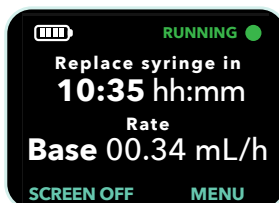
VYALEV is administered over 24 hours via subcutaneous infusion. It replaces scheduled levodopa-containing medications and any catechol-O-methyltransferase (COMT) inhibitors a patient is taking.^{1*}

VYALEV is dosed in units of milliliters per hour to establish a base continuous hourly infusion rate. The base **continuous hourly infusion** rate is calculated by determining the total levodopa dosage (current intake of levodopa and COMT inhibitors during waking hours), or TLD, and dividing it by the number of hours the patient is typically awake.¹

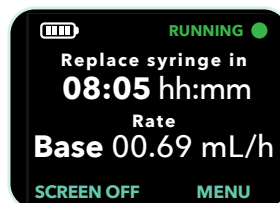
Base continuous hourly infusion rate examples



400 mg TLD



1000 mg TLD



2000 mg TLD

^{*}The maximum recommended daily dosage of VYALEV is 3525 mg of the foslevodopa component (equivalent to approximately 2500 mg levodopa). VYALEV may be administered over the patient's waking hours or may be administered for 24 hours. Prescribing a backup oral carbidopa and levodopa product is recommended in the event that delivery of VYALEV is interrupted, which may result in underdosing.¹

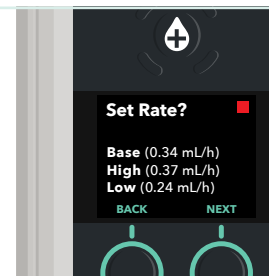
SAFETY CONSIDERATIONS (cont'd)

The **most common adverse reactions** for VYALEV (VYALEV incidence at least 10% and greater than oral carbidopa/levodopa incidence) were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, and dyskinesia.

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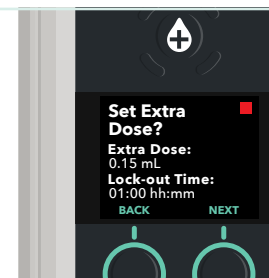
Please see HCP Pump Instructions for Use at https://www.rxabbvie.com/pdf/vyalev_hcp_vyafuserpump.pdf.

Optional dosing features



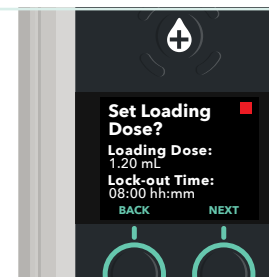
High/low continuous hourly infusion rates

Give your patients dosing flexibility throughout their day by allowing them to toggle between different continuous hourly infusion rates.¹



Extra dose

The delivery of an extra dose can be enabled. Extra doses range from 17 mg to 51 mg in levodopa equivalents.^{1,2}



Loading dose

Use a loading dose when starting VYALEV in an "Off" state or if the patient has not been receiving their base continuous infusion for more than 3 hours.¹

Dose programming

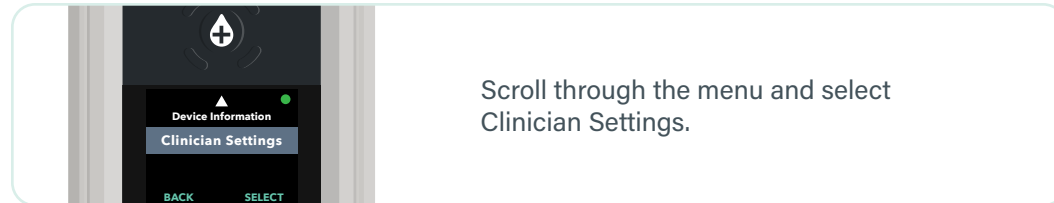
VYALEV dosing should only be programmed by a healthcare professional. On first use, the clinician must create a PIN to lock the dose settings. The same PIN will be required to access the Clinician Settings to confirm or adjust VYALEV dosing.²

When you prescribe VYALEV, the Specialty Pharmacy can program the pump with the dosing information and PIN that you provide on the Enrollment & Prescription Form. If you choose to program the pump yourself, you will be prompted to set a PIN when your patient first brings their pump to your office to start therapy. Once you set your PIN, follow the prompts to program the desired continuous hourly infusion rates as well as extra and loading dose parameters.²

The following section explains how to confirm a patient's dose and adjust as needed to help optimize their clinical response.

1

Access the Clinician Settings



Patients will not have access to Clinician Settings. They will select Change Rate in the menu to switch between base, low, and high continuous hourly infusion rates.²

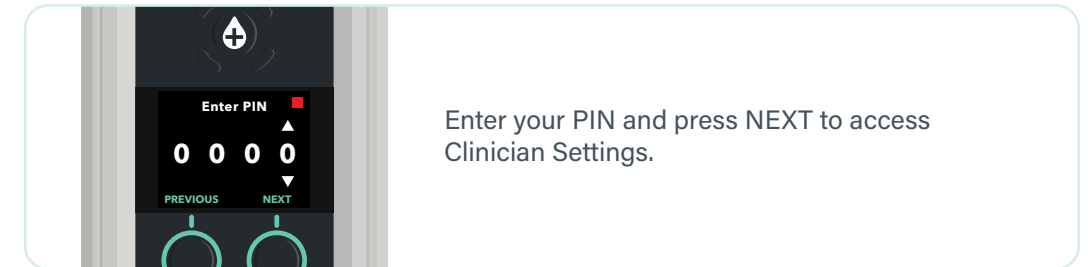
SAFETY CONSIDERATIONS

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2

Enter your PIN

Your PIN allows you to access Clinician Settings and change the dose parameters. Do not share the PIN with your patients as it is a safeguard to ensure that they cannot change the settings on their own.²



Note: If your patient has already initiated treatment, you will need to stop the continuous infusion before you can change the dosing parameters. The pump will prompt you to do this before you enter your PIN. Simply press YES to stop the pump. Wait a few moments until the red square appears in the upper right-hand corner of the screen.²



If you forget your PIN, call 1-866-489-2538. VYALEV will continue to be delivered to your patient at the previously programmed rate until you make changes.²

Please see additional Important Safety Information throughout. Please see accompanying Full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

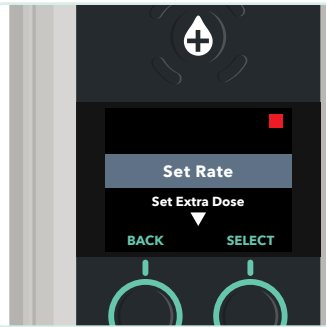
Please see HCP Pump Instructions for Use at https://www.rxabbvie.com/pdf/vyalev_hcp_vyafuserpump.pdf.



Dose programming (cont'd)

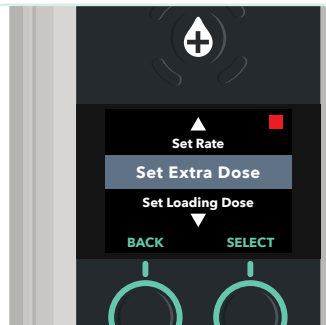
3

Confirm or adjust the continuous hourly infusion rates, extra dose, and loading dose volumes



Confirm or adjust the base and optional high/low continuous hourly infusion rates. Rates range from 0.15 mL/hr to 1.25 mL/hr and can be set in increments of 0.01 mL/hr (equivalent to 1.7 mg/hr of levodopa).^{1,2}

To disable high/low rates, set to same value as the base continuous hourly infusion rate.²



Confirm or adjust the optional extra dose volume and lockout time. Extra dose volumes range from 0.1 mL to 0.3 mL in increments of 0.05 mL (equivalent to 8.5 mg of levodopa), and lockout times range from 1 to 24 hours in increments of 15 minutes. Lockout times prevent patients from administering another dose until a set time has passed.^{1,2}

To disable the extra dose, set to 0.00.²



Confirm or adjust the optional loading dose volume and lockout time. Loading dose volumes range from 0.1 mL to 3.0 mL in increments of 0.1 mL (equivalent to 17 mg of levodopa), and lockout times range from 3 to 8 hours in increments of 1 hour.^{1,2}

To disable the loading dose, set to 0.00.²



Always verify that dose parameters have been set correctly. Press BACK to exit Clinician Settings to ensure that patients cannot adjust any of the values.²

SAFETY CONSIDERATIONS (cont'd)

VYALEV may cause **sudden falling asleep** during daily activities and somnolence; **hallucinations/psychosis**; compulsive behavior or **lack of impulse control**; **infusion site reactions and infections**; **withdrawal-emergent hyperpyrexia** and confusion; **dyskinesia**; **vitamin B6 deficiency** and **seizures**; **cardiovascular ischemic events**; or worsening **glaucoma**.

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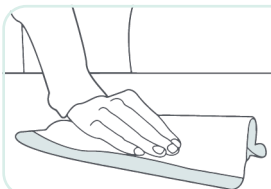
Please see HCP Pump Instructions for Use at https://www.rxabbvie.com/pdf/vyalev_hcp_vyafuserpump.pdf.

The 5 Ps of administration

Review the **5 Ps (Plan, Prepare, Prime, Place, and Pump)** and use them to help set your patients up for successful administration. Refer your patients to the Patient Pump Instructions for Use that they'll receive from the Specialty Pharmacy for additional information.

1

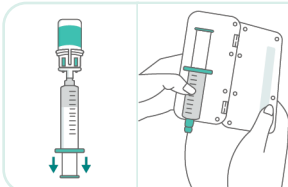
Plan it out



Clean your hands and working surface. Then, gather all the supplies.³

2

Prepare the syringe



Transfer all the medication from the vial to the syringe using the vial adapter. Attach the tip of the syringe to the tubing and place the full syringe inside the pump.³

SAFETY CONSIDERATIONS (cont'd)

The **most common adverse reactions** for VYALEV (VYALEV incidence at least 10% and greater than oral carbidopa/levodopa incidence) were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, and dyskinesia.

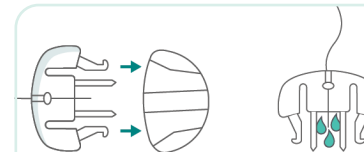
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Please see System Components Product Information at <https://www.devices.abbvie.com>, Battery Charger Instructions for Use at https://www.rxabbvie.com/pdf/vyalev_ifu_bcharger.pdf, and HCP Pump Instructions for Use at https://www.rxabbvie.com/pdf/vyalev_hcp_vyafuserpump.pdf.



3

Prime the tubing



Fill the infusion tubing with medication before connecting the cannula to the body.³

The infusion set may look different from the one shown here.

4

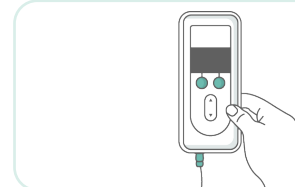
Place the cannula



Place the cannula on clean skin using the insertion device. Connect the tubing to the cannula.³

5

Pump the medication



Start the pump to deliver the medication.³



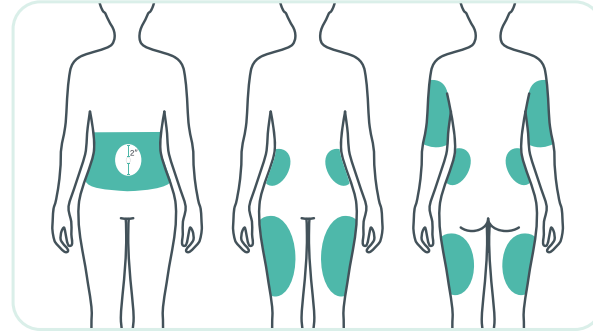
The medication vial, vial adapter, and syringe should be replaced at least once per day. The tubing, cannula, and insertion device should be replaced at least once every 3 days.¹

Infusion site care

1

Infusion Site Selection: Select intact skin, free of irritation; avoid scarred tissue, broken skin, stretch marks, bony areas, highly mobile areas, or skin folds.³⁻⁵ Choose a site where you can pinch at least an inch of skin and fat.⁵

The abdomen is a commonly used site, staying at least 2 inches from the navel. Select new infusion sites at least 1 inch from sites used within the previous 12 days.¹ The upper arm, thigh, and flank may be utilized.^{1,5,6*}



2

Infusion Site Preparation: Always clean the infusion site with water and antibacterial soap, followed by an alcohol pad prior to cannula placement, and ensure clean routine (wash, wipe, wait).^{1,4,5}

Wash: Wash hands with antibacterial soap and water. Clean the intended infusion site with water and antibacterial soap.^{3,5}

Wipe: Using clean hands, wipe the infusion site with an alcohol pad in an outward spiral motion—not back and forth—to avoid introducing bacteria into the site.^{3,5}

Wait: Allow the infusion site to air-dry for at least 60 seconds prior to cannula placement to ensure proper adhesion. Do not blow on or fan the area to accelerate drying.^{3,7}

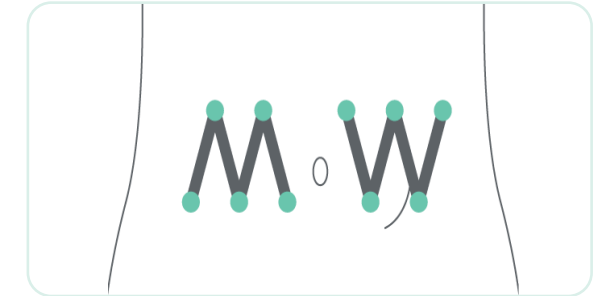
SAFETY CONSIDERATIONS

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3

Place Cannula Correctly: The 9-mm cannula is generally preferred, as it may help minimize dislodgement.⁴ Use 2 fingers to pull the skin tight and insert the cannula at a 90-degree angle, secure the site properly, and change the site if pain, irritation, or pooling occurs.¹⁴ Directly insert at site that was cleaned.^{3,7} Cover the infusion site with transparent film dressing (ie, TEGADERM®, OPSITE®) to secure the cannula and protect the site.⁴



Consider a pattern when rotating the infusion site.

4

Rotate Infusion Site and Remove Cannula:

Consider having patients rotate their cannula daily until good skin tolerability is achieved.^{4,5} After that, rotate at least every 3 days.¹ Leave previous cannula in place for 1 hour, and after removal, care for the skin by gentle massage (only on healthy skin) and consider applying a protective dressing.⁴

Develop a Plan

Patients: Regularly monitor infusion sites and seek prompt medical attention for spreading redness, pain, swelling, warmth, color change with pressure, or signs of fever.^{1,4,5,7}

HCPs: Develop a proactive plan with your patient to know who and when to call for help if symptoms worsen.¹

TEGADERM® is a registered trademark of Solventum.

OPSITE® is a registered trademark of T.J. Smith & Nephew Limited.

*In a phase 1 study, healthy volunteers were administered VYALEV to different subcutaneous sites (ie, abdomen, arm, and thigh) using a 3-way crossover design. Pharmacokinetic (PK) analysis from this study showed that the 3 sites provided comparable carbidopa and levodopa exposure, suggesting that VYALEV absorption is similar at the different subcutaneous sites.¹

Get your patients started

Once you've introduced your patient to VYALEV and they've become acquainted with the pump and administration, follow the steps below to get started with treatment initiation.

1 Complete the enrollment form

Evaluate vitamin B6 levels prior to initiation of VYALEV and during treatment.¹

- ✓ First, use the full Prescribing Information or VYALEV Dosing Calculator (VyalevCalculator.com) to **establish your patient's base continuous hourly infusion rate**
- ✓ Second, consider using VYALEV Pump features to provide **patients with dosing flexibility throughout their day**
 - **High and low continuous hourly infusion rates** can provide alternative flow rates from base; consider starting with +/- 10% from base infusion rate^{7*}
 - **Extra dose**, ranging from 17 mg to 51 mg in levodopa equivalents, can be enabled^{1,2}
 - **Loading dose** can be used when starting VYALEV in an "Off" state or if the patient has not been receiving their base continuous infusion for more than 3 hours¹
- ✓ Third, when the Enrollment Form is completed, **have your patient sign it**. Schedule your patient's Start Day **when they receive their product shipment**

SAFETY CONSIDERATIONS (cont'd)

VYALEV may cause **sudden falling asleep** during daily activities and somnolence; **hallucinations/psychosis**; compulsive behavior or **lack of impulse control**; **infusion site reactions and infections**; **withdrawal-emergent hyperpyrexia** and confusion; **dyskinesia**; **vitamin B6 deficiency and seizures**; **cardiovascular ischemic events**; or worsening **glaucoma**.

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Please see HCP Pump Instructions for Use at https://www.rxabbvie.com/pdf/vyalev_hcp_vyafuserpump.pdf.



2 Initiate VYALEV treatment on Start Day

- ✓ First, **review VYALEV administration and infusion site care** (including aseptic routine and site rotation) with your patient
- ✓ Second, **initiate dosing**
 - **Start with a loading dose or base rate**, depending on the motor state of your patient
 - If your patient is in the "On" state, immediately start with their base rate
 - If your patient is in the "Off" state, start with the loading dose, followed by their base rate
 - **Consider adjusting base rate and high/low rates** according to their initial response

In a clinical trial (n=55), **most patients (78%)** achieved final base rate within 2 or 3 visits (including Start Day)⁸

3 Follow up for VYALEV dose adjustments

- ✓ **When adjusting your patient's dose**, consider the following:

BASE RATE:

If a patient requires multiple (≥ 2 per day) extra doses on a routine basis, or primarily uses the high rate, consider increasing the base rate.¹

HIGH RATE:

Once the base rate is optimized, consider setting the high rate at 5% to 10% above the base rate for prolonged intense activity.^{1,7,9*}

LOW RATE:

Consider lowering the dosage at night. Consider starting at 10% to 30% below the base rate and adjusting as needed to achieve the desired response.^{1,7*}

*Recommendations are based on clinical experience of pivotal study investigators. Real-world infusion rates may differ. Refer to the Prescribing Information for further dosing guidance. Prescribing a backup oral carbidopa and levodopa product is recommended in the event that delivery of VYALEV is interrupted, which may result in underdosing.¹

IMPORTANT SAFETY INFORMATION AND INDICATION

INDICATION¹

VYALEV is indicated for the treatment of motor fluctuations in adults with advanced Parkinson’s disease (PD).

IMPORTANT SAFETY INFORMATION

Contraindications

VYALEV® (foscarbidopa/foslevodopa) is contraindicated in patients who are currently taking or have taken (within 2 weeks) a nonselective monoamine oxidase (MAO) inhibitor, as concurrent use can cause hypertension.

Warnings and Precautions

Falling Asleep During Activities of Daily Living and Somnolence: Patients treated with levodopa (the active metabolite of VYALEV) have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes resulted in accidents. Although many of these patients reported somnolence while on levodopa, some perceived that they had no warning signs, such as excessive drowsiness, and believed they were alert immediately prior to the event (sleep attack). Some of these events have been reported more than one year after initiation of treatment. For this reason, prescribers should continually assess VYALEV-treated patients for drowsiness or sleepiness. Advise patients about the potential to develop drowsiness with VYALEV and ask about factors that may increase risk of somnolence. Consider discontinuing VYALEV in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation. If VYALEV is continued, patients should be advised not to drive and to avoid other potentially dangerous activities that might result in harm if the patient becomes somnolent. There is insufficient information to establish that dose reduction will eliminate episodes of falling asleep while engaged in activities of daily living.

Hallucinations/Psychosis: There is an increased risk for hallucinations and psychosis in patients taking VYALEV. Hallucinations associated with levodopa may present shortly after the initiation of therapy and may be responsive to dose reduction of VYALEV or other concomitantly administered medications. Patients with a major psychotic disorder should not be treated with VYALEV.

Impulse Control/Compulsive Behaviors: Patients may experience intense urges while on VYALEV. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while on VYALEV. Consider reducing the dose or discontinuing VYALEV if a patient develops such urges.

Infusion Site Reactions and Infections: VYALEV can cause infusion site reactions and infections. Various types of reactions at the infusion site have been reported, including erythema, pain, edema, nodules, warmth, swelling, and others. The most frequent infusion site infection reported was cellulitis. If an infection is suspected at the infusion site, the cannula should be removed. In such a case, either a new cannula should be placed at a new infusion site or, in the event of a prolonged interruption, prescribe an oral carbidopa/levodopa product until the patient is able to resume VYALEV.

Withdrawal-emergent hyperpyrexia and confusion, a symptom complex that resembles neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction, withdrawal, or change in dopaminergic therapy. Avoid sudden discontinuation or rapid dose reduction of VYALEV.

Dyskinesia: VYALEV may cause or exacerbate dyskinesias, which may require a dose reduction of VYALEV or other medicines used to treat Parkinson’s disease.

Vitamin B6 Deficiency and Seizures: Treatment with carbidopa/levodopa (the active metabolites of VYALEV) may contribute to reduced vitamin B6 levels and higher doses of carbidopa/levodopa may increase the risk. Seizures associated with vitamin B6 deficiency have been reported in patients taking carbidopa/levodopa. Evaluate vitamin B6 levels prior to initiation of VYALEV and during treatment or if symptoms of vitamin B6 deficiency are identified and supplement with vitamin B6 as necessary.

Cardiovascular Ischemic Events: Myocardial infarction and arrhythmia were reported in patients taking carbidopa/levodopa (the active metabolites of VYALEV). Ask patients about symptoms of ischemic heart disease and arrhythmia, especially those with a history of myocardial infarction or cardiac arrhythmias.

Glaucoma: Monitor patients with glaucoma after starting VYALEV as it may cause increased intraocular pressure.

Adverse Reactions

The most common adverse reactions for VYALEV that occurred in ≥3% of patients, and at least 2% difference from oral immediate-release carbidopa/levodopa, were infusion/catheter site reactions, infusion/catheter site infections, hallucinations, dyskinesia, On and Off phenomenon, balance disorder, constipation, peripheral swelling, agitation, insomnia, psychotic disorder, and dyspnea.

Drug Interactions

- The use of nonselective MAO inhibitors is contraindicated. Use of selective MAO-B inhibitors may be associated with orthostatic hypotension.
- Concurrent administration with antihypertensives can cause symptomatic postural hypotension, which may require a dose adjustment of the antihypertensive.
- Coadministration with dopamine D2 antagonists or isoniazid may reduce the effectiveness of VYALEV.

Dosage Forms and Strengths

VYALEV (foscarbidopa and foslevodopa) injection for subcutaneous use is available in a 120 mg foscarbidopa and 2,400 mg foslevodopa per 10 mL (12 mg foscarbidopa and 240 mg foslevodopa per mL) solution.

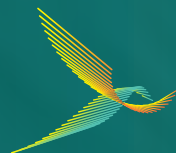
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

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Hotline at 1-866-489-2538
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