VYALEV® COMPLETE

Vyalev At-Home Dose Adjustment Order Form

Please sign and fax this form to 1-888-953-2762
For questions, please call 1-866-231-2418

Please print clearly. All fields marked with an asterisk (*) are required.

Patient Information

Name*: _____

Sex: ☐ Male ☐ Female **Pump PIN*:** _____

Date of Birth*: _____ /_____ /_____
Month Date Year

Address*: _____

City: _____

State: _____ ZIP*: _____

Phone #*: _____

Interpreter needed? ☐ Yes ☐ No

Language: _____

Prescriber Information

Prescriber Name*: _____

Check One: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other: _____

Address: _____

City: _____ State: _____ ZIP*: _____

NPI #: _____

Office Contact*: _____

Office Phone #*: _____ Fax #*: _____

Questions during At-Home Patient Support? Patient can call directly to:

_____

Dose Adjustment Instructions: By providing the instructions below, I understand that at the patient's request, an AbbVie-contracted Home Health Registered Nurse (an "HHRN") will provide technical support for patient-directed dose adjustment as instructed by me, the patient's Healthcare Professional (HCP). Infusion rates for the pump may be adjusted only according to these directions. If my patient requests adjustment outside the levels I have specified below, my patient will be referred back to me for additional consultation. I further understand that an HHRN does not provide medical advice, make diagnoses, perform general nursing services, or exercise clinical judgment, and my patient will be referred back to me for any medical questions or questions about their treatment plan. I also understand I will have no contact with the HHRN.

Accurately fill in all fields below to ensure timely support for your patient. The minimum programmable pump increment is 0.01 mL, which is equal to 1.7 mg of levodopa. The ordering HCP should specify the clinically appropriate dose adjustment volume. Adjustments greater than the minimum increment are permissible as determined by the treating clinician.

Base Rate

__.__ __ mL/hr (Current Rate)

☐ Adjust dose by __.__ __ mL/hr as needed to maintain the dose within a range of __.__ __ mL/hr to __.__ __ mL/hr.

☐ Check if you do NOT want the base rate adjusted.

Ordered base rate must remain within the ordered low-rate and high-rate parameters.

High Rate

__.__ __ mL/hr (Current Rate)

☐ Adjust dose by __.__ __ mL/hr as needed to maintain the dose within a range of __.__ __ mL/hr to __.__ __ mL/hr.

☐ Check if you do NOT want the high rate adjusted.

Low Rate

__.__ __ mL/hr (Current Rate)

☐ Adjust dose by __.__ __ mL/hr as needed to maintain the dose within a range of __.__ __ mL/hr to __.__ __ mL/hr.

☐ Check if you do NOT want the low rate adjusted.

If the patient reports experiencing any adverse events (AEs) during a home visit, I understand the HHRN will report the AE to AbbVie and direct the patient to call my office to discuss.

Nursing Orders: My signature on this form confirms my order (the "Order") for an HHRN to provide in-home VYAFUSER™ pump technical support at the above patient's request due to the patient's difficulty returning to my office for pump technical support. I am providing the HHRN the patient's pump PIN code and the above specific instructions for the dose adjustment based on my clinical judgment. This Order is valid for a maximum of five (5) patient home visits within forty-five (45) days from the date of signature below. This is not a standing order, and I agree this Order does not relieve me of my ongoing obligation to evaluate, monitor, and treat my patient. I understand I may modify or terminate this Order at any time, except this Order may not be extended beyond 45 days or 5 visits within a 45-day period.

Prescriber Certification: By my signature below, I certify: (1) I have examined the patient and am providing ongoing care; (2) patient support from an AbbVie-contracted third-party Home Health Registered Nurse (the "HHRN") is optional and offered at no charge for the benefit of the patient and is not required for the patient to receive the prescribed product; (3) the HHRN will not provide reports to me, but the VYALEV Complete hub will send me a confirmation that an HCP-ordered, patient-directed dose adjustment took place; (4) services performed by the HHRN are not eligible for reimbursement and I will not seek reimbursement from the patient or any third-party payer; and (5) at any time, I can separately order and direct a home health nurse of my choosing who would not be associated with the AbbVie-contracted HHRN, AbbVie, or any of its contracted vendors.

Prescriber's Signature*

_____ Date*: _____ /_____ /_____
Month Date Year

Please see Indication and Important Safety Information on page 2.
Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/vyalev_pi.pdf.

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

Indication[1]

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

Important Safety Information[1]

Contraindications[1]

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[1]

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.

Reference: 1. VYALEV [package insert]. North Chicago, IL: AbbVie Inc.

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VYALEV®
foscarbidopa/foslevodopa
Injection for subcutaneous use