



VYALEV™ COMPLETE

Your How-to Guide

Instructions, reminders, answers, and more

Before you administer VYALEV for the first time, you should be shown how to do it correctly by a healthcare provider. Before you start VYALEV, and also each time you get a refill, please use the Medication Guide and Instructions for Use that came with your drug vials, pump, and supplies from your Specialty Pharmacy.

USE

VYALEV is a prescription medicine used for treatment of advanced Parkinson's disease in adults. VYALEV contains two medicines, foscarnidopa and foslevodopa.

SELECT SAFETY INFORMATION

Do not use VYALEV if you take or have taken a nonselective monoamine oxidase (MAO) inhibitor within the last 14 days. Ask your healthcare provider if you are not sure if you take an MAO inhibitor.

Please see [Use and Important Safety Information on page 4](#) and [page 5](#), and full [Prescribing Information](#).



VYALEV™
foscarnidopa/foslevodopa
Injection for subcutaneous use
12 mg/240 mg per mL

What's inside your How-to Guide:

Use and Important Safety Information	4 →
Introduction	7 →
Your VYALEV team	8
What is your delivery system?	10
Delivery system overview	12
The 5 Ps	15 →
Overview of the 5 Ps	16
Plan It Out	18
Prepare the Syringe	20
Prime the Tubing	26
Place the Cannula	28
Caring for your infusion site	33
Pump the Medication	34

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





Additions to Your Routine 37 →

Additions to Your Routine overview	38
How to stop and restart your pump	39
How to replace the syringe only	40
How to disconnect and reconnect to your pump within 1 hour	43
How to replace the tubing and cannula (or disconnect and reconnect to your pump after 1 hour)	46
How to replace your syringe, tubing, and cannula	49
Pump dosing and flow rate options	52
Pump alarms and messages	56
Everyday life with your delivery system	66

Frequently Asked Questions (FAQs) 71 →

Infusion set FAQs	72
Medication FAQs	74
Pump FAQs	76

Additional Resources 79 →

Please see [Use and Important Safety Information on page 4 and page 5](#), and full [Prescribing Information](#).





USE

VYALEV is a prescription medicine used for treatment of advanced Parkinson's disease in adults. VYALEV contains two medicines, foscariidopa and foslevodopa.

IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know about VYALEV™ (foscariidopa/foslevodopa)?

Do not take VYALEV if you currently take or have recently taken (within the last 14 days) a medication for depression called a nonselective monoamine oxidase (MAO) inhibitor. Ask your healthcare provider or pharmacist if you are not sure if you take an MAO inhibitor.

Tell your healthcare provider about all your medical conditions and the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. When used together, VYALEV and certain other medicines, including medications for high blood pressure, MAO inhibitors, antipsychotics, metoclopramide, and isoniazid, may affect each other and cause serious side effects.

VYALEV may cause other serious side effects. Talk to your healthcare provider before starting VYALEV and while on VYALEV if you have had or have any of the following:

- **Falling asleep without warning during normal daily activities.** VYALEV may cause you to fall asleep while you are doing daily activities, such as driving, which may result in an accident. This can happen as late as 1 year after you start VYALEV. Do not drive or operate machinery until you know how VYALEV affects you. Tell your healthcare provider if you take medicines that can make you sleepy, such as sleep medicines, antidepressants, or antipsychotics.
- **Seeing, hearing, or feeling things that are not real (hallucinations). This is a common and sometimes serious side effect.**
- **Unusual urges.** Some people taking medicines for Parkinson's disease, including VYALEV, have reported problems, such as gambling, compulsive eating, compulsive shopping, and increased sex drive.
- **Infusion Site Reactions and Infections.** Some people using VYALEV have had reactions and infections at the infusion site. **This is a common and sometimes serious side effect.** Remove your cannula and **call your healthcare provider if you have any of the following symptoms of an infection:** local spreading of redness, pain, swelling, warmth, change in color when pressing area, or fever. Take oral carbidopa/levodopa tablets until you are able to resume VYALEV.
- **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 Parkinson's medicines may need to be adjusted.

(continued on next page)

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





- **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 eyes** (glaucoma). The pressure in your eyes should be checked after starting VYALEV.

Do not stop using VYALEV or change your dose unless you are told to do so by your healthcare provider. Tell your healthcare provider if you develop withdrawal symptoms, such as fever, confusion, or severe muscle stiffness.

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

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

Please see the full Prescribing Information, including Medication Guide, for additional information about VYALEV. Talk to your healthcare provider if you have questions.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call [1-800-FDA-1088](tel:1-800-FDA-1088).

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/PatientAccessSupport to learn more.





Introduction

In this guide, you'll find out how to use your delivery system. You'll also learn ways to establish your new routine. Throughout your treatment, you'll have 24/7 support and guidance from VYALEV Complete. The goal is to help you feel as prepared as possible as you move forward.

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- | | |
|----------------|---|
| <u>Page 8</u> | Your VYALEV team
A place to record your team's contact information |
| <u>Page 10</u> | What is your delivery system?
A description of all the supplies and how they work |
| <u>Page 12</u> | Delivery system overview
A look at how the delivery system supplies come together |

Please see [Use and Important Safety Information](#) on [page 4](#) and [page 5](#), and full [Prescribing Information](#).



VYALEV™
foscarnidopa/foslevodopa
Injection for subcutaneous use



Your VYALEV team

Caring support whenever you need it

Write down your team’s contact information here so it will be easy to find. Save their numbers in your phone, too. That way you’ll know to pick up when they call.



Healthcare provider

Name: _____

Phone number: _____



Specialty Pharmacy*

Name: _____

Phone number: _____



Nurse Ambassador†

Name: _____

Phone number: _____



If they’re not available, call the VYALEV Complete 24/7 Hotline‡ at **1-866-489-2538**. It’s staffed by nurses trained on VYALEV.

*A Specialty Pharmacy is a type of pharmacy that handles medication for conditions like advanced Parkinson’s. These medications often need special storage and processing.

†Nurse Ambassadors are provided by AbbVie and do not work under the direction of your health care professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

‡The 24/7 Hotline is staffed by nurses that are specifically trained on VYALEV and can be reached 24 hours per day, 7 days a week. After business hours, you may be asked to leave a message for a return call within 30 minutes.

Please see **Use and Important Safety Information on page 4 and page 5**, and full **Prescribing Information**.





Additional contact information

Name: _____

Phone number: _____

Name: _____

Phone number: _____

Important notes

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



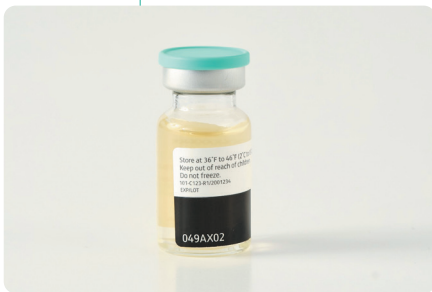


What is your delivery system?

The VYALEV Delivery System provides you with a continuous infusion **24 hours** a day, **7 days** a week. All these supplies work together to deliver your medication.

What supplies make up your delivery system?

Replace these supplies at least **once per day**



Medication vial

Contains the VYALEV solution that goes into a syringe



Vial adapter

Attaches to the vial and transfers the medication from the vial into the syringe



Syringe

Is filled with VYALEV and placed in the pump to push the medication through the tubing

Please see [Use and Important Safety Information on page 4](#) and [page 5](#), and full [Prescribing Information](#).



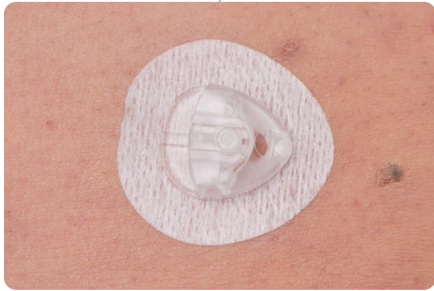
Infusion set

Replace these supplies at least **once every 3 days** or more frequently as directed by your doctor



Cannula insertion device

Helps insert the cannula into your body



Cannula

Is a tiny, flexible tube. It's inserted about a quarter of an inch into the skin to give you the medication



Infusion tubing

Connects the syringe to the cannula. The medication moves through this tubing



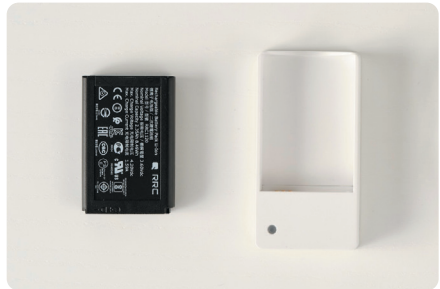
Pump

Is designed to give you your medication **24 hours** a day, **7 days** a week



Carrying case

Allows you to wear your pump a few different ways. Additional options are available



Rechargeable batteries

Power your pump and can be recharged. Always keep one charging while the other is in use

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



Delivery system overview

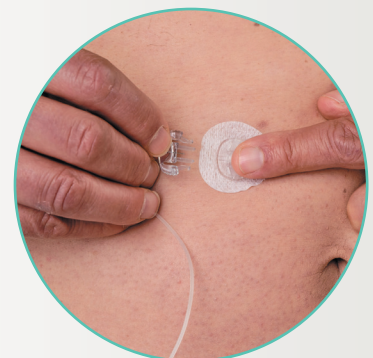
Here's a brief look at how your delivery system comes together. Find more instructions on the pages listed below.



The vial adapter attaches to the medication vial, [page 20](#)

The medication is transferred into the syringe, [page 21](#)

The tubing attaches to the tip of the syringe, [page 24](#)



The filled syringe is placed inside your pump, [page 25](#)

The cannula is placed into the skin of your belly, [page 28](#)

The site connector attaches to the cannula on your belly, [page 32](#)

Please see [Use and Important Safety Information on page 4 and page 5](#), and full [Prescribing Information](#).



Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



12
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B. BRAUN Omnitix™
DO NOT
REFUSE

Store at 36°F to 46°F (2°C to 8°C)
Keep out of reach of children
Do not freeze
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The 5 Ps

The instructions for administering VYALEV are broken down into 5 phases. These phases are called the 5 Ps. In this section, you'll learn about each one:

Page 16	Overview of the 5 Ps
Page 18	Plan It Out
Page 20	Prepare the Syringe
Page 26	Prime the Tubing
Page 28	Place the Cannula Caring for your infusion site, page 33
Page 34	Pump the Medication

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).



VYALEV™
foscarnidopa/foslevodopa
Injection for subcutaneous use



Overview of the 5 Ps

Your doctor will help you set up your delivery system in their office. They'll also start your continuous infusion. After that, you'll continue your routine at home using the 5 Ps. Here's an overview:



Plan It Out

Clean your hands and workspace. Gather and check your supplies



Prepare the Syringe

Transfer the medication into the syringe. Place it in your pump



Prime the Tubing

Fill the new tubing with medication



Place the Cannula

Put the cannula into your skin. Connect it to the tubing



Pump the Medication

Start your pump. Use its carrying case

Let's take a closer look at the 5 Ps ▶



Your clean routine

Practice your clean routine by using aseptic technique to prepare and administer VYALEV. This means keeping your hands and workspace clean. It can help reduce the risk of infection and irritation at your infusion site. Be sure to:

- ✓ Wash your hands thoroughly with soap and water for at least **20 seconds**. Scrub the front and back of both hands, between your fingers and under your nails. Dry with a new paper towel
- ✓ Thoroughly wash the infusion site with soap and water. Use an alcohol pad to wipe the area in an outward spiral (not back and forth) to avoid moving bacteria into the site
- ✓ Let the infusion site **air-dry for 60 seconds** before placing your cannula
- ✓ Keep the syringe tip and tubing ends from touching unclean surfaces. If that happens, you'll need to throw them out and get replacements



Phase 1

Plan It Out

In this phase, you'll clean your hands and workspace. You'll also gather and check your supplies.

- Wash your hands thoroughly with soap and water for at least **20 seconds**. Scrub the front and back of both hands, between your fingers and under your nails. Dry with a new paper towel
- Grab your medication vial. If it was refrigerated, let it sit at room temperature for **30 minutes** before you use it. Don't warm the medication up any other way. Remember to keep it out of direct sunlight
- Thoroughly clean a large, flat workspace, like a kitchen table or countertop. Dry it with a new paper towel
- Gather your supplies:

✓ Medication vial	✓ Infusion set	✓ Carrying case
✓ Vial adapter	✓ Pump	✓ New paper towels
✓ Syringe	✓ Pump battery	✓ Alcohol pads
- ⓘ *Don't open the packaging for your supplies until you're ready to use them*
- ⓘ *Optional: Consider transparent film dressing to make sure the infusion set stays in place*
- Check for damage and expiration dates on all your supplies. If something's damaged or expired, don't use it. Contact your Specialty Pharmacy for replacements
 - ⓘ *Make sure you have replacements for all your disposable supplies*



- Check your medication vial. Make sure it reads “**VYALEV**.” The VYALEV medicine might look different in color but does not affect how well the medicine works.
- The medication vial:
 - ⊗ Should NOT be cloudy
 - ⊗ Should NOT have particles or flakes
 - ⊗ Should NOT be expired
- To put a fully charged battery in your pump, match up the metal strips between the battery and the battery compartment. Insert the battery. You’ll hear a CLICK when it’s in place. You’ll hear the pump make start-up sounds. That means it’s getting ready for use
 - ⓘ *Always keep one battery charging while the other is in use. See more details on [page 66](#)*
 - ⓘ *Make sure the battery cover is fully closed*
 - ⓘ *Only use a fully charged battery. Be sure it’s one of the batteries that came with your pump, model RRC1120-PM*
 - ⓘ *Always fully charge your batteries. If you don’t, the battery and charger might not work right*
- Wash your hands a second time. Dry them with a new paper towel

Refer to your **Battery Charger** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





Phase 2

Prepare the Syringe

In this phase, you'll transfer your medication into the syringe. Then you'll place it in your pump.

Fill the syringe



- Take off the medication vial's cap



- Use an alcohol pad to clean the top of the vial
 ⚠️ *Wait 5 seconds for it to air-dry*



- Grab your vial adapter. Leave it in the outer protective packaging. Peel back the cover



- Hold the vial in one hand on a flat workspace. Hold the adapter by the outer protective packaging in the other hand. Place it on top of the vial. Press down until you hear a SNAP

Continued on next page

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





- Once you connect the vial adapter, the outer protective packaging can come off. The vial adapter will still be attached to the vial. Throw the packaging away in your regular trash

⚠ *Take care not to touch the exposed end of the vial adapter*

⚠ *Don't remove the adapter from the vial after it's been attached*



- Take your syringe out of its packaging

⚠ *Don't touch the syringe tip to any unclean surfaces. If it does touch, throw it away and get a new one*

- Push the syringe plunger all the way in to get the air out



- Flip the syringe vertically, with the tip pointing down
- While holding the vial, press the syringe tip into your vial adapter. Turn it clockwise as you go

⚠ *Don't overtighten the syringe in your vial adapter*



- Flip the syringe so the medication vial is now on top. Pull the syringe plunger all the way down, slowly. Withdraw all the medication from the vial. It'll fill the syringe to around the 12 mL mark. You'll see air at the tip of the syringe

⚠ *Always withdraw all the medication from the vial into the syringe*

Please refer to the Instructions for Use of VYALEV and **Vial Adapter** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



Remove large air bubbles

Check for large air bubbles in the medication. They may form when you're filling the syringe. Tiny air bubbles are okay. But large ones may affect your dosage and delay your medication's flow.



← Large air bubbles

To remove large air bubbles. . .



- Hold your syringe horizontally
- Slowly and gently rotate and tilt the syringe. Repeat this a few times until air bubbles gather at the tip
- ⓘ *Don't shake or tap the syringe to remove the air bubbles*



- If the air bubbles won't budge, hold the syringe vertically, with the tip facing down. Then rotate it so the tip is facing up. Gently turn it back and forth a few times



- All the large air bubbles should gather together. They'll float to the tip of the syringe and combine with the air there

Continued on next page



- Slowly press the plunger in. This will push the air out of your syringe and into the vial

ⓘ *Keep the syringe straight. Try not to tilt it. This prevents another air bubble from forming*



- Continue pushing until all the air is pushed out of the syringe and into the vial. You'll still see medication in the syringe tip

ⓘ *You might feel some resistance. That's normal. Keep going*

- Stop pressing the plunger when all the air is out



- Flip the syringe and vial. The vial should be right-side up on your workspace

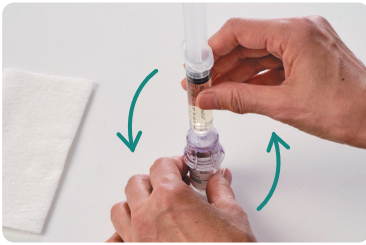
Please refer to the Instructions for Use of VYALEV, **Pump** Patient Instructions for Use, and **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





Connect the syringe and tubing



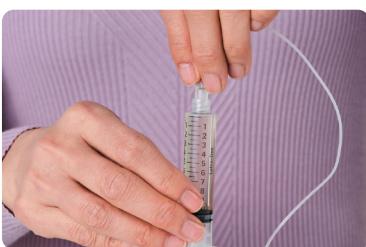
- Gently turn and pull the syringe counterclockwise to take it out. Be careful not to push the plunger or the medication will leak
- Carefully place the syringe on a new paper towel
 - ⓘ *Don't touch the syringe tip to any unclean surface. If it does touch, throw it away and get a new one*



- The tubing is packaged with the cannula insertion device. Take it out of the package and remove the paper
- The tubing has 2 different ends:
 - The pump connector end attaches to the syringe tip
 - The site connector end will attach to your cannula after it's been inserted



- ⓘ *Don't let the tubing ends touch any unclean surfaces. If that happens, you'll need to throw the tubing out and get a new one*
- ⓘ *The cannula and tubing must be replaced regularly, at least once every 3 days or more frequently as directed by your doctor*



- Hold your syringe with the tip pointing up
- Press the pump connector onto the syringe tip. Turn it clockwise as you push

Please refer to the Instructions for Use of VYALEV, **Pump** Patient Instructions for Use, and **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



Place the syringe inside your pump



- Press any button to turn the pump screen on
 - Press **"MENU"**
 - You'll see a few options. Highlight **"Insert Syringe"** and press **"Select"**

ⓘ *The pump screen will only show "Insert Syringe" if a syringe isn't inserted*



- Slide the latch to open the pump's lid
- Line up the wings (flanges) of the syringe with the pump grooves inside the pump

ⓘ *The syringe should fit into the pump groove with little to no resistance. If it doesn't, check to make sure:*

- ✓ *The air has been removed from the syringe*
- ✓ *The syringe plunger rod pusher in the pump is in the correct position*



- Make sure the syringe is correctly seated in the pump and close the lid. You'll hear a SNAP sound when it's fully closed



- Click **"YES"** to confirm the syringe is inside. Your pump will now prepare the syringe for use

Please refer to the Instructions for Use of VYALEV, **Pump Patient Instructions for Use**, and **Infusion Set Patient Instructions for Use** that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).

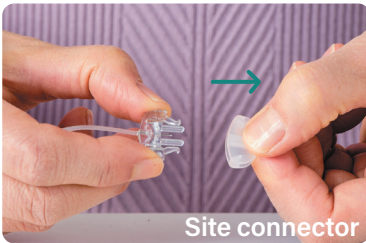




Phase 3

Prime the Tubing

In this phase, you'll fill the tubing with medication before connecting it to your body. You'll need to prime whenever you use new tubing. Your tubing should be replaced every time you change your cannula or more often, if needed.



- Take the white cover off the site connector end of your tubing. Squeeze the sides and slide it off
 - ⓘ *Keep the site connector's cover in a clean, safe place. You'll need it to cover the site connector when you disconnect from the pump*
- Place the site connector on a new paper towel
 - ⓘ *Don't let the tubing ends touch any unclean surfaces. If that happens, you'll need to throw it out and get a new one*
 - ⓘ *You may need to hold the tubing still with your finger so it doesn't move off the paper towel*



- Since you just inserted the syringe, the pump screen will ask if you'd like to prime the tubing. Click "**YES**"
 - The screen will ask you to confirm that the tubing isn't connected to the cannula. It shouldn't be connected when priming. Click "**CONFIRM**"
 - If you need to prime and you're not seeing this screen, go to the status screen. Select "**MENU.**" Scroll to and select "**Change Supplies.**" Then scroll to and select "**Prime Infusion Line**"



- Hold the pump with the syringe tip facing up. Press "**PRIME**" once
 - ⓘ *The pump screen will rotate so you can read it when priming*
 - ⓘ *Don't tilt the pump. If you do, the screen will let you know the syringe tip must point straight up in order to prime*

Continued on next page

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





- Medication will push through the tubing, from the syringe to the site connector. Wait a **few seconds** to see a drop of medication on the paper towel
 - If you don't see a drop after a **few seconds**, press "**NO**" on the pump to prime again



- When you see a drop of medication on the paper towel, your tubing is primed
 - Press "**CONFIRM**" on the pump. Then click "**YES**" when asked if a drop appeared
 - ⓘ *If you don't press "**CONFIRM**," the pump screen will ask if a drop appeared*
 - ⓘ *If you press "**NO**," the pump will return to the previous screen. This will let you continue priming until a drop appears*



- Lay your pump flat on your workspace
- Wait at least **1 minute**. Make sure the medication stops dripping from the site connector



- Without lifting the site connector from the paper towel, gently tap the tubing right where it meets the site connector. This will shake off any drops of medication
 - ⓘ *Be sure to shake the medication droplets off the site connector. If you don't, they could make the site connector sticky and hard to remove later*

Please refer to the **Pump Patient Instructions for Use** and **Infusion Set Patient Instructions for Use** that came with your supplies.

Please see **Use and Important Safety Information on page 4 and page 5**, and full **Prescribing Information**.

**Phase 4****Place the Cannula**

In this phase, you'll put the cannula into your skin. Then you'll connect the tubing.

The spot where you'll insert the cannula is called the infusion site. The preferred infusion site is on your belly. In some cases, your doctor may suggest inserting the cannula into another part of your body.

**Remember to practice your clean routine**

Use aseptic technique when preparing and administering VYALEV. This means keeping your hands and workspace clean to help reduce the risk of infection and irritation at your infusion site.

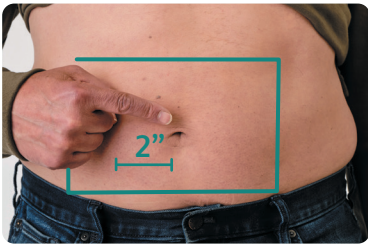
- Wash your hands thoroughly with soap and water for at least 20 seconds. Scrub the front and back of both hands, between your fingers and under your nails. Dry with a new paper towel
- Keep the syringe tip and tubing ends from touching any unclean surfaces. If that happens, you'll need to throw them out and get replacements
- Be sure to thoroughly clean your workspace. Dry it with a new paper towel
- When gathering your supplies, be sure to keep them in their packaging until you're ready to use them

Please refer to the **Infusion Set Patient Instructions for Use** that came with your supplies.

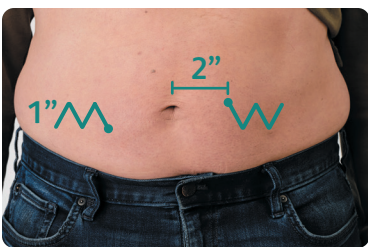
Please see **Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.**



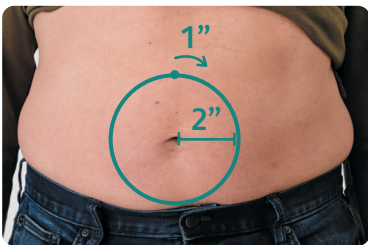
Choose your infusion site



- Always insert the cannula at least 2 inches away from your belly button. The distance from your fingertip to your knuckle is about 2 inches



- Rotate the infusion site. Choose an area that's at least 1 inch from previous sites used in the last **12 days**. The distance from the tip of your thumb to your knuckle is about 1 inch



- Consider rotating your cannula in a pattern:
 - "M" or "W"
 - Imagine a clock around your infusion site

Do NOT choose an infusion site within 2 inches of skin that. . .

- | | |
|---|---|
| <ul style="list-style-type: none"> ⊗ Is tender, bruised, red, or hard to the touch ⊗ Naturally bends, creases, or has skin folds ⊗ Has significant sweat | <ul style="list-style-type: none"> ⊗ Might interfere with clothing and cause irritation ⊗ Has body hair. Remove any body hair before inserting the cannula ⊗ Has stretch marks or scarring |
|---|---|

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





Get your skin ready to insert the cannula



- Thoroughly wash the skin of your infusion site with soap and water. Dry with a new paper towel

ⓘ *Don't touch your skin after you've washed it*



- Use an alcohol pad to wipe the infusion site in an outward spiral (not back and forth). This helps you avoid moving bacteria into the site

ⓘ *Don't touch your skin after using the alcohol pad*

- Let your skin air-dry for **1 minute** so that the tape on the cannula can stick properly

ⓘ *Don't blow on your infusion site to dry it*

ⓘ *Don't touch the center of your infusion site to see if it's dry*

Insert your cannula



- Remove the paper from the bottom of the cannula insertion device. This will expose the adhesive tape. Gently pull it in a circular motion so the tape doesn't stick to itself

ⓘ *Your tubing and insertion device will be packaged together. Throw away whichever piece you don't need*

ⓘ *Be careful not to touch the adhesive tape once the paper is removed*

Continued on next page

Please refer to the **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).



- Take off the safeguard at the top of the insertion device. Gently squeeze the sides and pull it straight out
 - ⓘ *Keep the safeguard in the clean, safe place where you stored the site connector cover earlier. You'll need both when you disconnect from your pump*



- Note the arrows on the insertion device. This shows the side of the cannula where the tubing will connect. Place the arrows on whichever side you'd like to connect your tubing



- Hold the insertion device in one hand. Gently stretch your skin with the other hand. This will create a taut, flat surface. Then hold the insertion device against your skin
- Press the red button down completely to insert the cannula. It'll make a CLICK sound as it's inserted
 - Keep the device pressed against your skin for **5 seconds**. This will help make sure the tape sticks

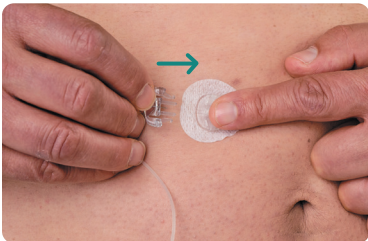


Insert your cannula (continued)



- Carefully pull the insertion device away from your body. The cannula and tape will stay on your skin. Press the tape down to make sure it's secure
- Throw away the insertion device in a sharps container*
 - ⓘ *If you tried to insert the cannula but it didn't work, don't use the same site again. Don't reuse the same cannula. Get a new insertion device. Place the new cannula in a different spot. It should be at least 1 inch from previous sites*
 - ⓘ *The tape may loosen or need to be readjusted or replaced. If that happens, remove the cannula. Insert a new cannula at a new infusion site*

Connect the tubing



- Place a finger on the cannula housing
- Push the site connector into the cannula housing. You'll know it's fully inserted when you hear a CLICK
- ⓘ *The site connector needs to be fully inserted. This will help keep any medication from leaking out*



- Your pump screen will ask you to confirm that the tubing is connected to the cannula
- Press "**CONTINUE**" to confirm

*A sharps container is a recycling bin for used needles and other medical supplies.

Please refer to the **Infusion Set** Patient Instructions for Use and the **Pump** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).



Caring for your infusion site



Check your infusion site often. Make sure:

- ✓ The cannula is still in place
- ✓ Fluid isn't leaking onto your skin
- ✓ The site isn't irritated

- ⓘ Consider transparent film dressing to make sure the infusion set stays in place
- ⓘ Replace your cannula and tubing at least **once every 3 days**. Your doctor may tell you to replace them more often (eg, daily or every other day) if you see signs of reaction, such as redness, or infection



Call your doctor if:

- You need help stopping your cannula from falling out
- You see signs of infection at the infusion site. This could include the spreading of redness, swelling, pain, warmth, and/or discoloration and may be accompanied by a fever. Change your cannula, too. Be sure to choose an infusion site at least 1 inch away from your previous site



For additional questions, call the VYALEV Complete 24/7 Hotline at **1-866-489-2538**. It's staffed by nurses trained on VYALEV.



Phase 5

Pump the Medication

In this phase, you'll start your pump. Then you'll place it in its carrying case.



- Now that you've connected the tubing, press any button to turn your pump screen on
 - Click "**MENU**"
 - You'll see a few options. Use the arrow keys to highlight "**Start Pump**" and press "**SELECT**"
 - Press "**YES**" to confirm you want to start the pump

ⓘ *Make sure the tubing is connected to the syringe and cannula. Make sure the tubing isn't blocked or tangled*



- The screen will say "**RUNNING**" in green in the top right corner. That's how you know the medication is flowing
 - Your medication will flow until your syringe runs out
 - The pump screen will go dark after **20 seconds** of inactivity. But the pump won't turn off unless the battery is removed. If you need to use your pump and the screen has timed out, press any button to turn the screen back on



- The pump screen will show a countdown of the time left until you need to replace your syringe. The timing depends on the dose or flow rate your doctor prescribed
 - The pump screen will show you the time left until your syringe is empty at the current rate. Or it'll show the time left until your syringe should be thrown out and replaced with a new one

ⓘ *Keep in mind, the medication **MUST** be used within 24 hours of being taken out of the vial, or it has to be thrown away*

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





- Unzip your carrying case. Place your pump inside. The buttons should be facing out so you can see them through the plastic window
 - Make sure the syringe tip is lined up with the opening on the side of the case
- Zip up the carrying case



- When wearing your pump, don't leave the tubing hanging loose. It could get caught on something and pull out your cannula
 - ⓘ *Make sure the tubing is connected to the cannula and syringe*
 - ⓘ *Check that the tubing isn't kinked or folded so the medication's flow isn't blocked*
 - ⓘ *Do not interact with the delivery system, including adjusting the dosage and/or addressing any alarms or informational messages, while operating motorized vehicles or machinery or otherwise engaging in any activities where distractions need to be avoided*
 - ⓘ *Additionally, to keep the cannula in place, you may wish to consider asking your HCP about transparent film dressing*

Please refer to the **Pump Patient Instructions for Use** and **Pump Carrying Case Patient Instructions for Use** that came with your pump.

Please see **Use and Important Safety Information** on **page 4** and **page 5**, and full **Prescribing Information**.





Additions to Your Routine

There are a few ways you'll need to maintain your routine throughout your treatment. In this section, you'll find:

Page 38	Additions to Your Routine overview
Page 39	How to stop and restart your pump
Page 40	How to replace the syringe only
Page 43	How to disconnect and reconnect to your pump <i>within 1 hour</i>
Page 46	How to replace the tubing and cannula (or disconnect and reconnect to your pump <i>after 1 hour</i>)
Page 49	How to replace your syringe, tubing, and cannula
Page 52	Pump dosing and flow rate options
Page 56	Pump alarms and messages
Page 66	Everyday life with your delivery system

Please see [Use and Important Safety Information on page 4](#) and [page 5](#), and full [Prescribing Information](#).



VYALEV™
foscarbidopa/foslevodopa
Injection for subcutaneous use



Additions to Your Routine overview

Here you'll learn a few more things about daily life with your delivery system. Like how to disconnect from your pump, replace your supplies, and more.



How to . . .

Stop and restart your pump whenever you disconnect from the pump or replace your supplies

Replace the syringe at least once every **24 hours**

Disconnect and reconnect to your pump *within 1 hour* like when you need to shower or swim

Replace the tubing and cannula at least **once every 3 days** or if you've been disconnected from the pump for **over 1 hour**

Replace your syringe, tubing, and cannula if you're changing all your disposable supplies at the same time



Pump dosing and flow rate options

Learn more about using an extra dose, loading dose, and different flow rates (if enabled by your doctor)



Pump alarms and messages

What they mean and what to do when they pop up



Everyday life with your delivery system

Tips for using your pump's batteries, what to do when traveling, and more

Let's take a closer look at Additions to Your Routine ▶

Please refer to the **Pump Patient Instructions for Use** that came with your supplies.

Please see **Use and Important Safety Information** on **page 4** and **page 5**, and full **Prescribing Information**.





How to stop and restart your pump

You'll need to stop and restart your pump whenever you replace your supplies or disconnect from the delivery system.



Remember, if you stop your infusion for **more than 1 hour**, be sure to replace the cannula and infusion tubing. If you don't, they could get clogged.



- To **stop** your pump. . .
 - Press any button to turn your pump screen on
 - Press "**MENU**"
 - Highlight "**Stop Pump**" and press "**SELECT**"
 - The pump screen will ask you to confirm that you want to stop the pump. Press "**YES**"
 - The pump will stop your medication's flow. You should see a red "**STOPPED**" in the top right corner



- To **restart** your pump. . .
 - Press any button to turn your pump screen on
 - Press "**MENU**"
 - Highlight "**Start Pump**" and press "**SELECT**"
 - Press "**YES**" to confirm you want to start the pump again
- ⓘ *If disconnected for more than 1 hour, replace your cannula and tubing. If you don't, a blockage may occur. See instructions on [page 46](#)*
- ⓘ *Before starting your pump, make sure the tubing is connected to the cannula and syringe. Make sure it isn't blocked*



How to replace the syringe only

You'll need to replace your syringe at least once every **24 hours**. You may need to replace it more often if it's empty or almost empty. It is also possible that at the end of the 24 hours, there will be medication left in the syringe that will need to be thrown away. It depends on the dose and flow rates prescribed by your doctor. Start getting a new syringe ready about **30 minutes** before the medication is about to run out. This is so your therapy will not be interrupted.

 If you're disconnected for **more than 1 hour**, replace your cannula and tubing. If you don't, a blockage may occur. See instructions on [page 46](#).


 Follow the **Plan It Out** phase on [page 18](#)

- This time, you'll only need to gather your:

- | | | |
|-----------|-------------------|--------------------|
| ✓ Pump | ✓ Medication vial | ✓ New paper towels |
| ✓ Syringe | ✓ Vial adapter | ✓ Alcohol pads |

 Follow the **Prepare the Syringe** phase on [page 20](#)



- Then press any button to turn the pump screen on
 - Press the **"MENU"** button
 - You'll see a few options. Highlight **"Change Supplies"** and press **"SELECT"**
 -  *When changing supplies, it's important to follow the display screens in order. This can help make sure the pump is set up the right way*
 - Press **"YES"** to confirm you want to stop the pump

Please refer to the Instructions for Use of VYALEV, **Pump** Patient Instructions for Use, and **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





- Highlight **“Remove Syringe”** from the menu options. Press **“SELECT”**
 - Don’t open the pump lid until the screen prompts you to
- Pause to allow the pump plunger to retract. A status bar will show its progress
- The pump screen will prompt you to open the lid. Slide the latch and remove the used syringe
- Disconnect the tubing from the used syringe
 - It’s okay if there’s some medication left in your syringe when it’s time to replace it
 - Do not use the medication left in your syringe
 - Throw away your used syringe according to your local guidelines



- Hold your new, filled syringe with the tip pointing up
 - Grab the pump connector end of the tubing. Attach it to the new syringe tip by pressing and turning it clockwise
- ⓘ *Don’t let the tubing ends touch any unclean surfaces. If that happens, you’ll need to throw out your tubing and get a new one*
- ⓘ *You don’t need to prime the tubing because you’re using the same tubing and only replacing the syringe*

Keep reading ▶



- Slide the latch to open the pump's lid
- Line up the wings (flanges) of the syringe with the pump grooves inside the pump

ⓘ *The syringe should fit into the pump groove with little to no resistance. If it doesn't, check to make sure:*

- ✓ *The air has been removed from the syringe*
- ✓ *The syringe plunger rod pusher in the pump is in the correct position*



- Make sure the syringe is correctly seated in the pump and close the lid. You'll hear a SNAP sound when it's fully closed
- Click **"YES"** to confirm that a new syringe is in. The pump will prepare your medication for use

- The pump will ask if you need to prime. Select **"NO"** if you only replaced the syringe and not the tubing

- The pump will ask if you want to start. Press **"YES"**

ⓘ *Make sure the tubing is connected to the cannula and syringe*

ⓘ *Check that the tubing isn't kinked or folded so the medication's flow isn't blocked*

Please refer to the Instructions for Use of VYALEV, **Pump** Patient Instructions for Use, and **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





How to disconnect and reconnect to your pump *within 1 hour*

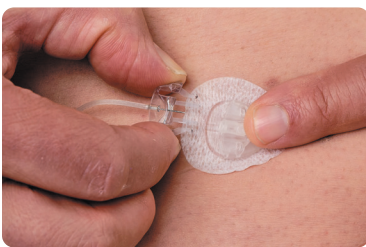
You'll need to disconnect from your pump when you want to shower or swim. You can't get in the water with your pump or tubing. But your cannula can get wet after being properly disconnected from the tubing.

- ⚠ Only use these instructions when you want to disconnect for **less than 1 hour**. If disconnected for **more than 1 hour**, replace your cannula and tubing. If you don't, a blockage may occur. See instructions on [page 46](#).

Disconnect the tubing from the cannula



- Press any button to turn your pump screen on
 - Press "**MENU**"
 - Highlight "**Stop Pump**" and press "**SELECT**"
 - Click "**YES**" to confirm you want to stop the pump



- Thoroughly wash your hands with soap and water
- Remove the site connector from the cannula housing
 - Gently place one finger on the cannula housing so it doesn't move
 - Squeeze the sides of the site connector. Pull it straight out



- Once the site connector is removed, lay it on a new paper towel
- Gently tap the tubing at the site connector end. This will shake off any drops of medication so it won't get sticky
 - Wait **60 seconds**. Then put the site connector's white cover back on

Please see [Use and Important Safety Information on page 4 and page 5](#), and full [Prescribing Information](#).



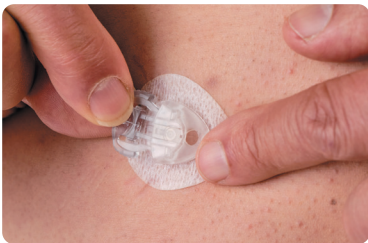
Get your cannula ready



- Insert the clean safeguard into the cannula. That's the transparent cover that came with the insertion device. You'll hear a **CLICK** when it's in all the way. That means you did it right, and your cannula is ready to get wet

- Keep the tubing and pump in a clean, dry place until you're ready to reconnect
- **Keep track of the time** after you disconnect. There are two ways to reconnect depending on how long you've been disconnected

Reconnect to your pump *within 1 hour*



- Thoroughly wash your hands with soap and water
- Remove the safeguard that's covering your cannula



- Take the cover off the site connector at the end of your tubing
- Gently place a finger on the top of the cannula housing. Push the site connector straight into the cannula. You'll hear a **CLICK** when it's in

Continued on next page



- Press any button to turn your pump screen on
 - ⓘ *Before starting your pump, make sure the tubing is connected to the syringe and cannula. Make sure it isn't blocked*
 - Press "**MENU**"
 - Highlight "**Start Pump**" and press "**SELECT**"
 - Press "**YES**" to confirm you want to start the pump
 - The pump will continue your infusion. It'll also count down the time left on your syringe

What to do if your site connector is stuck

If it's hard to pull out your site connector, the medication might have made it sticky. Here's how to fix it.

- Run a clean cloth under really warm water until it's dripping wet
- Let the wet cloth soak on the site connector for at least **2 minutes** to help dissolve the sticky medication. Gently rub the cloth, too
- Squeeze the sides of the site connector and try to pull it out
- If it's still stuck, try soaking and applying the cloth again

Please refer to the **Pump** Patient Instructions for Use and **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



How to replace your tubing and cannula (or disconnect and reconnect to your pump *after 1 hour*)

You'll need to replace your tubing and cannula whenever you're disconnected from your pump for **over 1 hour**. You'll need to replace these supplies at least **once every 3 days** or more frequently as directed by your doctor.



Follow the **Plan It Out** phase on [page 18](#)

- This time, you'll only need to gather your:
 - ✓ Pump
 - ✓ Infusion set
- ✓ Alcohol pads
 - ✓ New paper towels



- Press any button to turn your pump screen on
 - Press "**MENU**"
 - If your pump is running, highlight "**Stop Pump**" and press "**SELECT**"
 - Press "**YES**" to confirm you want to stop the pump. You should see a red "**STOPPED**" in the top right corner



- Take the pump connector end of the tubing off the syringe tip
 - Turn it counterclockwise, and pull it off



- Carefully loosen the tape on the cannula housing from your skin. Like you would when pulling off a bandage

Please see [Use and Important Safety Information on page 4 and page 5](#), and full [Prescribing Information](#).



- Pull the cannula housing away from your body to remove it
 - Throw out these supplies properly according to your local guidelines
- ⓘ *Once removed, check the cannula housing and infusion site to make sure no parts were left behind. If you think the cannula was detached from the housing unit and is still under your skin, call your doctor*
- ⓘ *Call your doctor if you see signs of infection at the infusion site such as the spreading of redness, swelling, pain, warmth, and/or discoloration, which may be accompanied by a fever*



- Attach new tubing to the syringe tip. You won't be replacing the syringe
 - Twist clockwise until it's snug. Be careful not to overtighten it



Follow the **Prime the Tubing** phase on [page 26](#)

- ⓘ *If you need to prime and you're not seeing the priming screen, go to the status screen. Find and select "**Prime Infusion Line**"*
- ⓘ *Wait 60 seconds. Tap the site connector with your finger. This removes drops and helps prevent the site connector from getting sticky*

Please refer to the **Pump Patient Instructions for Use** and **Infusion Set Patient Instructions for Use** that came with your supplies.

Please see **Use and Important Safety Information on page 4 and page 5**, and full **Prescribing Information**.



Follow the **Place the Cannula** phase on [page 28](#)

- Remember to choose an infusion site that's at least 1 inch from previous sites used in the last **12 days**



- Once the tubing is connected to the cannula. . .
 - Press "**CONTINUE**" on your pump screen to confirm it's connected
 - !** *Before starting your pump, always make sure the tubing is connected to the cannula and syringe. Make sure it isn't blocked*
 - Then press "**YES**" to start the pump

If you have been disconnected for 3 or more hours or if you are initiating therapy in an "Off" state, administer a loading dose before starting the base continuous infusion. This should either be provided via the pump if programmed by your HCP or by using an oral supply of immediate-release carbidopa/levodopa.

Please refer to the Instructions for Use of VYALEV, **Pump** Patient Instructions for Use, and **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





How to replace your syringe, tubing, and cannula

Use these steps when you're replacing all your disposable supplies. Your tubing and cannula need to be replaced at least **once every 3 days** or more frequently as directed by your doctor. Your pump will let you know when to change your syringe.



You should start about **30 minutes** before your medication is due to run out. This way, you won't have to go without your medication while you get the next syringe ready.



Follow the **Plan It Out** phase on [page 18](#)



Follow the **Prepare the Syringe** phase on [page 20](#)



- To **stop** your pump. . .
 - Press any button to turn your pump screen on
 - Press "**MENU**"
 - Highlight "**Stop Pump**" and press "**SELECT**"
 - Click "**YES**" to confirm you want to stop the pump. You should see a red "**STOPPED**" in the top right corner



- Carefully loosen the tape on the cannula housing from your skin, like you would when pulling off a bandage

Please see [Use and Important Safety Information on page 4 and page 5](#), and full [Prescribing Information](#).



- Pull the cannula housing away from your body to remove it
 - Practice your clean routine using aseptic technique
 - ⓘ *Once removed, check the cannula housing and infusion site to make sure no parts were left behind. If you think the cannula was detached from the housing unit and is still under your skin, call your doctor*
 - ⓘ *Call your doctor if you see signs of infection at the infusion site such as the spreading of redness, swelling, pain, warmth, and/or discoloration, which may be accompanied by a fever*



- To take the old syringe out of your pump. . .
 - Press **"MENU"**
 - Highlight **"Change Supplies"** and press **"SELECT"**
 - Follow the prompts to highlight the **"Remove Syringe"** menu. Press **"SELECT"**
 - Pause to allow the pump plunger to retract. A status bar will show its progress



- Your pump will prompt you to open the lid. Slide the latch and take out the old syringe
 - Throw away your used syringe and infusion set according to your local guidelines



- Attach new tubing to the new, filled syringe
 - Twist clockwise until it's snug. Be careful not to overtighten it

Continued on next page



- Place the new syringe inside the pump. Line up the syringe wings with the grooves. The tip that's connected to the tubing will stick out

ⓘ *The syringe should fit into the pump groove with little to no resistance. If it doesn't, check to make sure:*

- ✓ *The air has been removed from the syringe*
- ✓ *The syringe plunger rod pusher in the pump is in the correct position*



- Make sure the syringe is correctly seated in the pump and close the lid. You'll hear a SNAP sound when it's fully closed
- Press **"YES"** to confirm the new syringe is inside the pump
 - Pause to let the pump prepare the new syringe



Follow the **Prime the Tubing** phase on [page 26](#)



Follow the **Place the Cannula** phase on [page 28](#)

- Remember to choose an infusion site that's at least 1 inch from previous sites used in the last **12 days**



- Once the tubing is connected to the cannula, confirm it's connected by pressing **"CONTINUE"** on your pump

ⓘ *Before starting your pump, make sure the tubing is connected to the cannula and syringe. Make sure it isn't blocked or tangled*

- Press **"YES"** to start your pump

Please refer to the Instructions for Use of VYALEV, **Pump** Patient Instructions for Use, and **Infusion Set** Patient Instructions for Use that came with your supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).



Pump dosing and flow rate options

Flow Rates

Your pump is programmed to give you your medication at your prescribed dosage, called the base rate. But your doctor may have programmed your pump with additional flow rates. If available, you can use these flow rates to change the amount of medication your pump delivers. If you're unsure, call your doctor.

High Rate

If your pump has a high rate option, it'll give you more medication. This could be used when engaging in physical activities for a while.

Low Rate

If your pump has a low rate option, it'll give you less medication. This could be used at nighttime.

Here's how to change your flow rates if they were set up by your doctor:



- Press any button to turn your pump screen on. Then press **"MENU"** to see a few options
 - ⓘ *You don't need to stop the pump to change the flow rate*
 - Use the arrow keys to highlight **"Change Rate."** Press **"SELECT."** Then follow the instructions on the screen
 - Confirm you want to change the rate. Press **"YES"**
 - Use the arrow keys to highlight the desired rate. Press **"SELECT"**
 - Confirm by pressing **"YES"**

Please refer to the **Pump Patient Instructions for Use** that came with your supplies.

Please see **Use and Important Safety Information** on [page 4](#) and [page 5](#), and full **Prescribing Information**.





Extra Dose

Your doctor may have set up your pump to allow for an extra dose. An extra dose is a small dose of medication delivered over a short amount of time.

Here's how to start an extra dose if this option was set up by your doctor:



- While the pump is already running, press the extra dose button
 - ⓘ *The pump must be delivering your continuous infusion in order to administer an extra dose*
 - ⓘ *Your pump screen will show the time left until you can get another extra dose. Extra doses can't be delivered too close together. This is called the lockout time. If it's too early, the extra dose feature will be locked out*
 - ⓘ *If the extra dose feature isn't available, the screen will let you know*
 - ⓘ *If there isn't enough medication in the syringe for an extra dose, you'll need to replace the syringe first*



- To start the dose, press the extra dose button a second time. You'll hear your pump make a sound. That means it started the extra dose
 - A status bar will appear on the screen. It'll show the progress of the extra dose delivery
 - You'll hear your pump make a sound when the extra dose is complete



Extra Dose (continued)

- Press “**OK**” when the extra dose is complete
 - ⓘ *If you don't press “OK” within 20 seconds, the pump will resume your continuous infusion*
- If you need to cancel the extra dose after it's started, press “**CANCEL**”
 - Press “**YES**” to confirm you'd like to cancel
 - ⓘ *If the extra dose is canceled, it can't be resumed. The next extra dose also can't be started until the lockout time is over*
 - Resume the continuous infusion by pressing “**YES**” when asked if you'd like to start your pump
 - ⓘ *Press “NO” only if you don't want to resume the continuous infusion*

Loading Dose

Your doctor may have set up your pump to allow for a loading dose. A loading dose is a large dose of medication that's delivered faster than a typical dose. If enabled, you can use this if you're starting therapy or if your pump has been off for at least **3 hours** or more as directed by your doctor and you're starting in an “Off” state.



If your pump is stopped for **more than 1 hour**, you need to replace the cannula and tubing.

- To see if a loading dose is available, choose “**Start Pump.**” If it's available, the screen will show it as an option. You can't start a loading dose unless the pump shows that it's available
- You can take your loading dose through the option on your pump if programmed by your doctor or by using oral immediate-release carbidopa/levodopa as advised by your doctor

Continued on next page



Here's how to start a loading dose if this option was set up by your doctor:



- Press any button to turn your pump screen on. Then press **"MENU"** to show a few options
 - Highlight the **"Start Pump"** option. Press **"SELECT"**
 - Press **"YES"** to start your loading dose
 - A bar will appear and begin to show the progress of the loading dose
 - Loading doses can't be delivered too close together. Your pump screen will show the time left until you can get another loading dose. This is called the lockout time. If it's too early, the pump won't give you the option to start a loading dose
 - The pump will let you know when the loading dose is complete. If you don't press **"OK,"** the pump screen will return to the status screen after **20 seconds**

- If you need to cancel the loading dose after it's started, press **"CANCEL."** Then press **"YES"** to confirm
 - ⓘ *If the loading dose is canceled, your pump will stop delivery. It won't automatically start your continuous infusion*

- To resume a loading dose, turn your pump screen on. Then press **"MENU"** to see a few options
 - ⓘ *If you start your continuous infusion after canceling the loading dose, your pump won't show the loading dose option until the lockout time has expired*

- Highlight the **"Start Pump"** option. Press **"SELECT."** Then press **"YES"** to resume
 - ⓘ *The loading dose will continue from the point where it was canceled*
 - ⓘ *If you select **"NO,"** the pump will prompt you to confirm you do NOT want the loading dose and instead want to start a continuous infusion*

Please refer to the **Pump Patient Instructions for Use** that came with your supplies.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





Pump alarms and messages

Your pump screen will show you a few types of notifications throughout your day. You'll also hear a notification sound. Here's what each notification means and what you should do when it pops up.



Informational messages let you know what your pump is doing. You'll hear *2 beeps* for these messages.



Low priority alarms let you know that there will soon be a problem. You'll hear *2 tones* for these messages. If action is not taken as indicated in the alarm message, it may lead to a high priority alarm.



High priority alarms let you know that your pump has stopped delivering your medication. Take action right away to resolve it. You'll hear *3 tones, a short pause, then 2 tones*. This alarm will then repeat.



You cannot hear the alarm for 1 minute but you still need to address the alert.

If action is needed, your screen will provide instructions on what to do. Please refer to the **Pump Patient Instructions for Use** that came with your pump.



When you see these notifications, you'll need to. . .

Mute

Press any button but “OK” to mute your alarm. It'll be temporarily silenced but you'll still see the alarm icon.

Acknowledge

Press “OK.” The alarm will be silenced and the icon will disappear. It'll pop up again if the problem isn't fixed.

Resolve







Follow the on-screen instructions and perform corrective action.

Do NOT interact with the delivery system, including adjusting the dosage and/or addressing any alarms or informational messages, while operating motorized vehicles or machinery or otherwise engaging in any activities where distractions need to be avoided.

Let's take a closer look at your pump's notifications ▶






Dosing messages

Pump message	What to do
<p> Extra Dose delivery complete.</p>	<p>Your pump has delivered your extra dose. Press "OK" to continue.</p>
<p> Extra Dose is already running.</p>	<p>Your extra dose is being delivered. Allow the current extra dose to finish. Press "OK" to continue.</p>
<p> Extra Dose is not available while Loading Dose is running.</p>	<p>You cannot administer an extra dose while the loading dose is being delivered. Wait for the loading dose to finish.</p>
<p> Extra Dose is not enabled.</p>	<p>Extra doses are set by your doctor when they program your pump. Ask them if this option should be available to you. Press "OK" to leave the screen.</p>
<p> Extra Dose is only available while Pump is running.</p>	<p>You need to turn your pump on before it can give you an extra dose.</p>
<p> Insufficient Solution remaining to deliver Extra Dose.</p>	<p>There isn't enough medication to give you an extra dose. Please change to a full syringe.</p>

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



Dosing messages (continued)

Pump message	What to do
 Insufficient Solution remaining to deliver Loading Dose.	There isn't enough medication to give you the loading dose. Please change to a full syringe.
 Loading Dose delivery complete.	Your pump has finished delivering your loading dose. You can press " OK " to continue.
 Next Extra Dose will be available in: Xx:yy hh:mm	You cannot get an extra dose until the lockout time expires. Check the time and countdown shown on your pump screen. Press " OK " to continue.



Pump messages

Pump message	What to do
(No message, screen is blank and unresponsive)	Replace the battery with a fully charged battery. If your pump still doesn't respond, remove the battery. Wait 10 minutes . Then reinsert the fully charged battery. Restart your pump. If that doesn't work, call your doctor, Ambassador, or the 24/7 Hotline if they are not available.







Continue for more pump messages ►

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.








Pump messages (continued)

Pump message	What to do
<p> Pump disabled. Refer to instructions.</p>	<p>Your pump is disabled due to pump failure. To troubleshoot this issue as quickly as possible, it's best to call your doctor, Ambassador or the 24/7 Hotline if they are not available.</p>
<p> Pump has exceeded service life. Please refer to your instructions.</p>	<p>Your pump will continue to work, but it has reached the end of its designed life and should be replaced as soon as possible. Call your doctor, Ambassador, or the 24/7 Hotline if they are not available.</p>
<p> Pump is tilted. Syringe tip must point straight up.</p>	<p>Your pump is tilted and the syringe is not pointing in the correct direction during priming. Reposition your pump so the syringe tip is pointed straight up.</p>
<p> Canceling...</p>	<p>The action has been canceled. You don't need to do anything.</p>
<p> Lid open. Close lid to continue.</p>	<p>Close your pump's lid and follow the on-screen prompts.</p>
<p> Pump waiting for input. Please complete current task.</p>	<p>Your pump needs additional input. Select "OK" to continue.</p>

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



Pump messages (continued)







Pump message	What to do
 <p>Flow is blocked! Pump is stopped. Remove blockage.</p>	<p>Your pump has stopped because something is blocking the flow of medication into your system. Inspect the tubing for kinks. Open the pump lid to make sure there's no blockage in the syringe housing. If the problem continues, replace the tubing and cannula. If blockage is found in the tubing, check section 8.12 in Troubleshooting of your Patient Instructions for Use.</p>
 <p>Lid open. Pump is stopped. Close lid.</p>	<p>Your pump has stopped delivering medication because the lid is open. Close the lid. Contact your doctor, Ambassador, or the 24/7 Hotline if the alarm continues after closing the lid properly.</p>
 <p>Problem detected. Pump is stopped.</p>	<p>Your pump has detected a problem and is not delivering your medication. Press "OK" and follow the instructions to reset your pump. You may need to do this more than once. Make sure you're using a fully charged battery. Contact your doctor, Ambassador, or the 24/7 Hotline if the alarm doesn't stop.</p>

Please refer to the **Pump** Patient Instructions for Use that came with your pump.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





Syringe messages

Pump message	What to do
 No syringe detected.	Your pump hasn't detected a syringe. If there is a syringe in your pump, open the lid and make sure it's placed correctly. If there is no syringe, insert a syringe.
 Syringe error. Please wait.	Your pump cannot tell if a syringe has been loaded or not. Wait for your pump to return to the status screen. Go to the "Insert Syringe" option on the menu, and follow the "Change Syringe" instructions on the screen.
 Prepare new Syringe soon.	The syringe has been in your pump for 23 hours . You will need to replace the syringe within 1 hour .
 Replace Syringe.	The syringe has been in your pump for 24 hours , which means it needs to be thrown away. Replace your syringe.
 Syringe will be empty within 45 minutes.	At the current delivery rate, your syringe will be empty within 45 minutes . You'll need to prepare a new syringe. If your medication vial is refrigerated, allow it to warm to room temperature for 30 minutes first.
 Syringe will be empty within 2 hours.	At the current delivery rate, your syringe will be empty within 2 hours . You'll need to get a new syringe ready soon.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.




Syringe messages (continued)

Pump message	What to do
 Priming error. Pump is stopped.	The pump is not yet primed or is not priming as expected. See if the syringe is leaking where it connects to the tubing. If it is, wipe it clean, tighten the connection and prime again. If it is not leaking, repeat priming until the air is removed.
 Syringe is empty! Pump is stopped. Replace Syringe.	Your pump has stopped because the syringe has run out of medication. Replace the syringe right away.








Battery messages

Pump message	What to do
 Battery degraded. Order a replacement battery soon.	The battery is not keeping a charge as expected. Replace the battery with a fully charged one. You may need to contact your Specialty Pharmacy to order a new replacement battery.

Continue for more battery messages ►





Battery messages (continued)

Pump message	What to do
 Battery is removed. Insert battery.	Your battery is missing. If there is a battery in your pump, take it out, wait for the screen to go blank and put it back in. If that doesn't work, replace the battery.
 Remove battery. Await blank screen. Re-insert battery. Refer to instructions.	Follow the on-screen instructions and wait for the pump to restart. If the problem is fixed, replace the syringe with a new one. If not, the pump will reset the time remaining to next syringe change to 24 hours, so you won't be notified when the old syringe runs out. If the problem continues, contact your healthcare provider.
 Battery Error. Replace battery.	You need to replace your pump's battery. Replace the battery with a fully charged one.
 Low Battery. Less than 4 hours remaining.	Check that your second battery is charging. You will need to use a fully charged battery to replace the battery in your pump within 4 hours .
 Low Battery. Less than 30 minutes remaining. Replace Battery soon.	Your pump will stop within 30 minutes because your battery is running extremely low. Replace it with a fully charged battery or make sure you have one ready. When running faster rates, the battery will run out more quickly.



Battery messages (continued)

Pump message	What to do
 <p>Battery is removed. Pump is stopped. Insert battery.</p>	<p>Your pump is stopped because it cannot detect a battery. If there is a battery already in your pump, remove it, wait for the screen to go blank and put it back in. If that doesn't work, replace the battery.</p>
 <p>Battery empty! Pump is stopped. Replace battery.</p>	<p>Replace with a fully charged battery right away.</p>

Please refer to the **Battery Charger** Patient Instructions for Use that came with your pump.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.





Everyday life with your delivery system

Here's some information on building a routine and using your delivery system throughout your day.

When to change your supplies



Replace your syringe at least *once per day*.

You may have to replace it more often if it's empty or almost empty, depending on your dosage. Find more details on [page 40](#).



Replace your tubing and cannula at least *once every 3 days* or more frequently as directed by your doctor.

You'll also need to replace them if you're disconnected from the pump for **over 1 hour** or as directed by your doctor. Be sure to replace the tubing whenever you change your cannula. Find more details on [page 46](#).

How to use your pump's batteries

- Your pump comes with 2 rechargeable batteries
 - It only uses one at a time
 - Each battery takes **3 hours** to fully charge. A full charge will last about **24 hours**
 - Your pump will let you know when your battery is running low. See [page 56](#) for a full list of your pump's alarms and messages
- Always keep one battery charging while the other is in use. This way you'll have a charged battery ready when you need it
 - Choose the same time to replace and recharge your batteries. Like after you brush your teeth, replace your syringe, or when you're getting ready for bed. This will help it become part of your daily routine
 - When you leave your house, take an extra charged battery with you. If you're traveling for more than **24 hours**, be sure to bring your battery charger

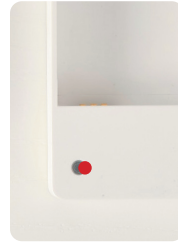
Please see [Use and Important Safety Information on page 4 and page 5](#), and full [Prescribing Information](#).



- The battery charging station has a light on it. It shows the battery's status with different colors and flashing signals. Here's what they mean:



Light off:
The battery isn't charging



Red light, without battery in charging station:
There's no battery inserted, but the charging station is ready



Red light, with battery in charging station:
The battery is bad or there's a problem charging



Orange light:
The battery is correctly charging. The light might blink red when the battery is first inserted



Green light:
The battery is fully charged and ready to go into your pump



To reduce the risk of electric shock or other harm:

- Don't use the battery charging station if it looks damaged
- Don't use battery charging stations that are different from the AC/mains adapter and battery charger that came with your pump

Note: If the syringe has been removed during battery replacement or the pump does not detect the syringe after the battery is replaced, the screen will show **"Insert Syringe"** instead of **"Start Pump."** If this happens, replace the syringe with a new one.

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



Traveling with VYALEV

Whether you're going on a long trip or just leaving the house for a little while, you'll need to prepare a few things.

Pack a to-go bag:

- Think about how long you'll be out. Count how many infusion sets, medication vials, vial adapters, and syringes you'll need. Bring enough to last the whole time you'll be away from home
 - Your medication vials can be stored at room temperature for up to **28 days**
 - Don't forget alcohol pads and a fully charged spare battery
 - If you're going to be gone for a day or more, bring your battery charging station, too
- Bring a prescribed supply of oral carbidopa/levodopa immediate-release tablets with you in case you can't use your delivery system
- Keep your packed to-go bag in a convenient place where you'll remember to grab it. This way you'll be ready to head out whenever you need to

Tips for flying

When traveling by air, your delivery system will still work on your plane and during your flight. But your pump and its batteries cannot go through the screening machines at airport security. You'll need to request a different screening process that allows you to stay connected to your pump. You'll also need to pack your supplies correctly.

Here's how you can prepare:

- **72 hours** before your flight, call the Transportation Security Administration (TSA) at 855-787-2227. Let them know you're using a medical device that cannot go through the screening machines and you'll need an alternative screening process

Please see [Use and Important Safety Information on page 4](#) and [page 5](#), and full [Prescribing Information](#).





- Pack your medication and supplies in your carry-on bag. They CANNOT be packed in checked luggage, which could get lost, delayed or exposed to temperatures that might damage them
- Pack your spare pump battery and charging system in a separate carry-on bag from your other supplies. They cannot go through the screening machines at security. Your other supplies can go through the machines
- Pack the TSA Notification Card and Medical Alert Card your Ambassador gave you

On the day of your flight:

- Try to reduce the chance that you'll need to change your supplies at the airport or during your flight. Plan to replace any supplies you may need to change before heading out
- Arrive at the airport early. You'll need plenty of time to go through security
- Once you get to security, remind the TSA personnel that you'll need an alternative screening process. Show them your TSA Notification Card
- Ask to board the plane early so you can keep your carry-on bags with you. Your supplies can't go in checked luggage



Reach out to your Ambassador for more tips and resources to help.



If you're traveling within the US for more than **28 days**, ask your Specialty Pharmacy about shipping your medication to your destination.





Frequently Asked Questions (FAQs)

Here are answers to common questions about your medication, pump, and infusion set.

Page 72

Infusion set FAQs

Using your cannula, insertion device, and tubing

Page 74

Medication FAQs

Using your medication vial and syringe

Page 76

Pump FAQs

Using your pump, batteries, and carrying case

Please see [Use and Important Safety Information](#) on [page 4](#) and [page 5](#), and full [Prescribing Information](#).



VYALEV™
foscarnidopa/foslevodopa
Injection for subcutaneous use



Infusion set FAQs

How often do I need to replace the infusion tubing?

You can replace the tubing as often as you need to. But you should replace the tubing and cannula at least **once every 3 days** or more often if your doctor recommends it.

What do I do if my tubing and/or cannula get pulled out?

If either gets pulled out, turn your pump off so you don't lose any medication. Then replace the entire infusion set, including the tubing and cannula. Remember to place the new cannula at least 1 inch away from previous site.

When do I have to prime the tubing?

Prime whenever you're using new tubing.

What if I can't remove the site connector from the cannula when I'm trying to disconnect?

- Apply a warm, wet cloth to the site connector for at least **2 minutes**
- Gently squeeze the cloth and rub the site connector in a circular motion to let the water soak into it
- Try to detach it again
- If that didn't work, repeat these steps one more time
- If that still didn't work, remove and throw away the cannula and tubing

See more details on [page 47](#)

Please refer to the **Medication Guide** and Instructions for Use that came with your pharmacy supplies.

Please see **Use and Important Safety Information** on [page 4](#) and [page 5](#), and full **Prescribing Information**.





What if I can't disconnect the tubing from the syringe when replacing my supplies?

There are two reasons the pump connector might be hard to disconnect from the syringe tip. It might be sticky from medication. Or you may have overtightened it when attaching it to the syringe tip. Try to unscrew it by following these steps:

- Hold a warm, damp cloth in your hand and try to unscrew the pump connector. Turn it counterclockwise
- If that doesn't work right away, let the damp cloth soak on the pump connector for a little bit. Then try to unscrew it again
- If you still can't disconnect it, you'll need to replace your syringe and infusion set. Follow the "**How to replace your syringe, tubing, and cannula**" steps on [page 49](#)

What should I do if my delivery system is leaking or if the tubing is blocked?

If the delivery system is leaking, try to locate the source of the leak.

If the leak is happening where the tubing is connected to the syringe, make sure the connection is tight and secure.

If the cannula or tubing is leaking, replace the infusion set. You'll also need to do this if the tubing is blocked or damaged. Follow the "**How to replace your tubing and cannula (or disconnect and reconnect to your pump after 1 hour)**" steps on [page 46](#).



Medication FAQs

How many syringes will I need to use per day?

Everyone is different. Your care team will explain how often to change your syringe based on your dosage. But once the medication is in the syringe, it's only good for **24 hours** and must be thrown away after.

Can I reuse a syringe?

No, each syringe is single use. Once the medication is inside the syringe, you must use it within **24 hours**. If you don't use it all within **24 hours**, throw away the syringe and medication left by following your local regulations.

How should I store my medication?

Keep your medication vials in the outer carton to protect them from breaking. Store them in the refrigerator at 36 °F to 46 °F (2 °C to 8 °C).

You can keep your medication vial at room temperature, up to a maximum of 86 °F (30 °C), for up to **28 days**. Once a vial is stored at room temperature, don't put it back in the refrigerator. *DON'T FREEZE your medication. If it does freeze, you'll have to throw it away.* Do not use after expiration date on vial or supplies.

What if I can't use my refrigerator?

Contact your Specialty Pharmacy right away for detailed instructions. If necessary, you can keep your medication vial at room temperature, up to a maximum of 86 °F (30 °C) for up to **28 days**. Once a vial is stored at room temperature, don't put it back in the refrigerator. **DON'T FREEZE** your medication. If it does freeze, you'll have to throw it away.

Please refer to the **Medication Guide** and Instructions for Use that came with your pharmacy supplies.

Please see **Use and Important Safety Information on page 4 and page 5**, and full **Prescribing Information**.





How do I store my medication when traveling by plane?

Pack your medication in its outer packaging and carton. Be sure you always pack it in your carry-on bag. It could freeze or get too hot in your checked bag. If it freezes or gets too hot, you'll have to throw it away.

What do I do if my syringe doesn't fit in the pump?

There are 2 common reasons the syringe may not fit.

1. Be sure to line up the wings of the syringe with the grooves in the pump. The syringe plunger rod pusher may not be fully retracted. In that case, close the lid without the syringe in the pump, and follow the instructions on the pump display, pressing the button to indicate that there is no syringe in the pump.
2. There may be air in the syringe tip. Reattach the syringe to the vial adapter that's still attached to the vial. With the vial and syringe pointed upward, slowly push the rest of the air out of the syringe until there's solution visible in the syringe tip. Then reattach the tubing and try again. Make sure you're using the right syringe that was included with your supplies.

Please refer to the **Medication Guide** and Instructions for Use that came with your pharmacy supplies.

Please see **Use and Important Safety Information** on **page 4** and **page 5**, and full **Prescribing Information**.





Pump FAQs

What do I do if my fully charged battery lasts less than 24 hours?

If your battery isn't holding a charge, contact your Specialty Pharmacy for a new one.

What if I install a fully charged battery and the pump doesn't power on?

Check the strips on the battery and pump. If there is a contaminant or something else blocking contact between the battery and pump contacts, try to remove it. Make sure your battery is inserted the right way. Take it out and put it back in. If that doesn't work, your battery may be dead. Contact your Specialty Pharmacy right away for a new one. Keep a prescribed supply of oral carbidopa/levodopa immediate-release tablets with you in case you're unable to use your delivery system.

When should I charge the pump's batteries?

Each battery takes **3 hours** to fully charge. A full charge will last about **24 hours**. You should replace your battery at the same time each day. Pick a time that's easy to remember, like when you're getting ready for bed. This way, it'll become part of your routine. You should always keep one battery charging while the other one is in your pump. That way you'll have a battery ready to use when you need it.

What do I do if my pump stops working?

Make sure the pump is on. It can get turned off by accident. Or see if it needs new batteries. If neither of these are causing the problem, contact your doctor and Specialty Pharmacy. Keep a prescribed supply of oral carbidopa/levodopa immediate-release tablets with you in case you're unable to use your delivery system.

Please refer to the **Medication Guide** and Instructions for Use that came with your pharmacy supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





What do I do if my pump gets wet?

If your pump gets a little wet, wipe everything dry with a new paper towel. If it goes completely under the water and stops working, call your doctor, Specialty Pharmacy, or the 24/7 Hotline if they are not available.

What if I'm going to do something that could get the pump wet, such as taking a shower or going swimming?

Your pump and tubing can't get wet, but your cannula can. Follow all the "**How to disconnect and reconnect to your pump *within 1 hour***" steps on [page 43](#).

Do I always need to disconnect the pump before bathing or showering?

Yes. The pump can't get wet. You can go into water if you've properly disconnected your pump and tubing. Follow all the steps in "**How to disconnect and reconnect to your pump *within 1 hour***" on [page 43](#). If you're going to be disconnecting for longer, follow all the steps in "**How to replace your tubing and cannula (or disconnect and reconnect to your pump *after 1 hour*)**" on [page 46](#).

Is the pump sensitive to temperature?

The pump is made to work as intended within a temperature range of 41 °F to 104 °F (5 °C to 40 °C) within the humidity range of 15% to 90%.

Please refer to the **Medication Guide** and Instructions for Use that came with your pharmacy supplies.

Please see Use and Important Safety Information on [page 4](#) and [page 5](#), and full [Prescribing Information](#).





Pump FAQs (continued)

What should I do if I drop or hit my pump?

Check your pump for damage. If it's damaged, don't use it. Call your doctor or Specialty Pharmacy. Keep a prescribed supply of oral carbidopa/levodopa immediate-release tablets with you in case you're unable to use your delivery system.

What if I need to stop using my pump for a long period of time, like *more than 1 hour*?

If you want to stop using the pump and power it off completely, stop the pump, remove the battery and replace the battery cover. Talk to your doctor to make sure it's okay. Keep a prescribed supply of oral carbidopa/levodopa immediate-release tablets with you in case you can't use your delivery system. Follow all the steps in "**How to replace your tubing and cannula (or disconnect and reconnect to your pump after 1 hour)**" on [page 46](#).

Please refer to the **Medication Guide** and Instructions for Use that came with your pharmacy supplies.

Please see **Use and Important Safety Information** on [page 4](#) and [page 5](#), and full **Prescribing Information**.





The resources you need, when you need them

Learning to use your delivery system may seem like a lot at first. But VYALEV Complete is here to help. Take a look at these videos on www.VYALEV.com/Delivery-System. They can help you get familiar with the information in this guide.

Video 1: Getting Started

An overview of how the VYALEV Delivery System works and the support you have through VYALEV Complete

Video 2: How to Use Your VYALEV Delivery System

A step-by-step walk-through of how to administer your treatment at home, including:

- The 5 Ps
- How to replace your supplies
- How to disconnect and reconnect to your pump
- How to use your pump's alarms and dosing options—and more

Video 3: Routine Reminders

Tips on everyday life with your delivery system, including what to do when showering, sleeping, traveling and more



Scan to watch the videos

Feel free to read along as you watch.

Please see [Use and Important Safety Information on page 4](#) and [page 5](#), and full [Prescribing Information](#).





VYALEV[™] COMPLETE

Please see Use and Important Safety Information on page 4 and page 5, and full Prescribing Information.



VYALEV[™]
foscarbidopa/foslevodopa

Injection for subcutaneous use
12 mg/240 mg per mL

abbvie

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