



Step-by-step with your VYALEV treatment

A guide to using VYALEV and its delivery system

VYALEV is a medicine containing two active ingredients, foslevodopa and foscarbidopa, used to treat people with advanced Parkinson's disease.

This booklet is only intended for people prescribed VYALEV for advanced Parkinson's disease and their carers. The information provided does not replace the advice of your prescribing specialist or the information in the VYALEV Consumer Medicine Information (CMI). The CMI is available from your pharmacist or at abbv.ie/au-vylv-cmi.

Your care team is your primary support every step of the way. They can help you with questions or concerns about your condition and treatment. Always consult your prescribing specialist if you have any questions.



One step at a time

This booklet will aim to guide you through your new treatment and its delivery system. You will find important information about the VYAFUSER® Pump, step-by-step administration of VYALEV as well as additional support to help you get started on this treatment.



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Your infusion pump

An overview of the different items you will need to administer VYALEV and how to use your VYAFUSER® Pump.





Introduction

VYALEV is used to treat advanced Parkinson's disease, helping you to gain control over your movements and posture.

VYALEV is a solution (liquid) that goes through an infusion pump and a tube under your skin (subcutaneously). Your prescribing specialist will calculate the dose of VYALEV that you will use based on your individual needs. Your prescribing specialist or a member of their support team will train you on proper use of VYALEV and the delivery system prior to initiating treatment with VYALEV.

Your supplies

These items are required for administering VYALEV.



VYAFUSER® Pump

Delivers VYALEV medicine from the syringe, through the infusion set and into the infusion site.



Solution vial

Contains 10 mL of VYALEV medicine.



Vial adapter*

Attaches to the VYALEV solution vial and used to transfer your medicine from the vial to the syringe.



Syringe*

Used to draw VYALEV medicine from the vial.

^{*}Items may look different to the ones shown here.

Infusion set*



Tubing

Connects the syringe in the pump to the cannula, to deliver your medicine.



Insertion device and cannula

Used to insert the cannula into your body. The cannula is a small plastic tube that allows your medicine to flow into your body.

The infusion set may also be called an infusion line.



Rechargeable batteries and charging items*

Used as the power source for operating the pump. A fully charged battery should last at least 24 hours. While one of your two batteries is in the pump, charge the other battery until needed.

You should always follow sterile (aseptic) techniques while using VYALEV and regularly change the infusion site (at least every third day), using a new infusion set.

Make sure the new infusion site is at least 2.5 cm from a site used in the last 12 days. You may need to change the infusion site more often than every third day. Always talk to your prescribing specialist if you have any questions about your condition or treatment.

^{*}Items may look different to the ones shown here.

Your VYAFUSER® Pump

Front



Extra dose button: Used to deliver extra doses as required. This will be determined by your prescribing specialist.

Display: Contains pump status information and options for user action.

Selection buttons: Used to select between different choices on the display.

Up/down arrow keys: Used to scroll through menu options or to increase or decrease a value.

Lid: The pump is a clamshell design that opens for inserting and removing the syringe. This part, with the display, buttons and arrow keys, is referred to as the lid.

Lid latch: The lid latch can be slid to release the lid closing lock.

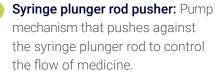
If you have technical issues with the delivery system that cannot be resolved using the Pump Instructions for Use (IFU), you can reach out for support.

Back and interior



Battery cover: Slides into place to close the battery compartment.

Syringe opening: The location where the tip of the syringe that connects to your infusion set tubing sticks out from your pump.



Pump information: Includes model and serial number.

Syringe flange grooves: Houses the syringe flanges and ensures proper alignment of the syringe when inserted into the pump.

Contact your prescribing specialist if:

- You notice any changes in the performance of the delivery system or unexpected events.
- You need to replace your pump and/or return it.

Contact an AbbVie Care nurse consultant if:

 You need assistance setting up the delivery system, using or maintaining the pump, or missing any components.

Caring for your pump

Your pump cannot get wet

You may temporarily detach from your pump to do things like shower, bathe or engage in water activities. Stop the pump and detach the infusion set tubing from the cannula before engaging in any activities in which the pump may get wet. It's okay if the cannula gets wet.





Only stay disconnected from your pump for less than one hour



If you are disconnected from your pump for longer than one hour, make sure to change your infusion set (tubing, insertion device and cannula) and rotate to a different infusion site before resuming infusion.



If you are disconnected for more than 3 hours, you may need to also self-administer a loading dose to quickly re-establish your symptom control.



Do not stop using VYALEV unless your prescribing specialist tells you to.



Resume the infusion when you've completed your task

If your pump gets wet, dry it off with a towel. If you accidentally drop the pump and it is submerged in water or any other liquid, call your prescribing specialist.

Understanding your pump display

Make sure you know how to read your pump display before starting your treatment administration.



Getting familiar with the status screen

The status screen is the main screen that appears on your pump display.

- Battery icon: Shows the status of the charge of your battery and warns when it is running low. Yellow outline and one yellow bar = battery could be depleted within 4 hours. Yellow outline and no bars = battery could be depleted within 30 minutes. Replace immediately.
- **Display ON/OFF:** Pressing the left selection button turns the display off, which helps save battery power. The display will turn off after 20 seconds of inactivity.

Note: This will not turn the pump off, only the display. Press any button to turn on the display.

Pump status: Shows whether your pump is running or stopped.

Note: On other screens, the top right corner will display only a green circle (for pump running) or red square (for pump stopped).

- **Syringe replacement information:** Shows the hours and minutes left until the syringe will be empty or the time left to change your syringe.
- **Current rate:** Displays the infusion rate that is being pumped in millilitres per hour (mL/h).
- **Pump menu:** Pressing the MENU button will display additional menu options.

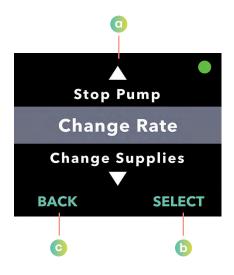
Interacting with your pump display

How to select from menu options



Status screen

Pressing the 'MENU' button will display the pump menu options. The pump menus are used to make changes in therapy and supplies.



Main 'MENU' options screen

- Up/Down arrow displays:
 Indicates when there are
 additional menu options
 above or below what's
 being shown on the screen.
- b Select display: When menu options are displayed, pressing the pump button below 'SELECT' will choose the highlighted menu option. The highlighted option is changed by pressing the arrow keys on your pump.
- Back display: Pressing the pump button below 'BACK' returns you to the status screen.

Other important icons that may appear on your screen

Your pump may make an alarm sound and display alert symbols if anything goes wrong. The alert symbol will have information about why it has appeared.



High priority alarm with audible tones (red)

Pump has stopped. Take action to resolve.



Low priority alarm with audible tones (yellow)

Pump is running. If action is not taken as indicated in the alarm message, it may lead to high priority alarm.



Alarm acknowledged but not resolved

Audible tones are silenced by pressing any button.



Informational message with audible tones

Provides status information.



Pump delivery methods

The pump delivers VYALEV in one of three ways:

Loading dose

A loading dose is a large single dose given shortly before your continuous infusion over a short period of time that may be prescribed by your prescribing specialist. If you are disconnected from your pump for more than 3 hours, you may need to self-administer a loading dose to quickly re-establish your symptom control.

If you have been prescribed a loading dose, you will only see this option when you start your pump after it has been stopped for more than 3 hours. It is not part of any menu.

Continuous infusion

A continuous infusion is delivery of VYALEV that runs throughout the day and night. You may be able to select or change your infusion rates, depending on your needs and your prescribing specialist's instructions. Always talk to your prescribing specialist if you have questions about your treatment, including infusion rate options. If this option has been made available to you by your prescribing specialist, you may be able to select from up to 3 options.

Base: The regular, daily infusion rate of VYALEV.

High: A steady, increased amount of your base infusion. **Low:** A steady, lowered amount of your base infusion.

Your pump doesn't have to stop to change your continuous infusion rate.



Select 'Change rate' from the 'MENU' and 'YES' to confirm.



Use the arrow keys to select either the 'high', 'base' or 'low' rate. Once you pick your rate, select 'YES'.

3 Extra dose

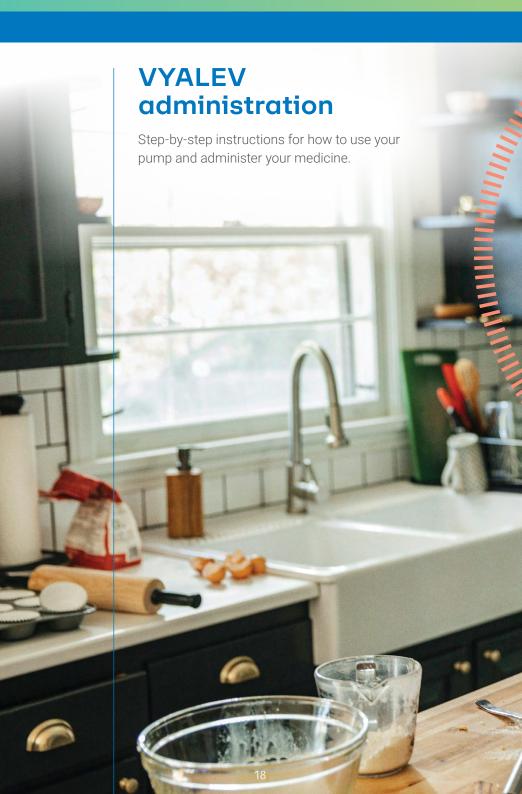
Usually, VYALEV is given as a steady hourly infusion rate. If needed, your prescribing specialist may decide that you are able to administer extra doses. An extra dose is a single, additional amount of medicine to help manage Parkinson's symptoms if they suddenly come up during your continuous infusion. Extra doses are optional.



The extra dose button is located at the top of your pump. Press it once to request an extra dose, then follow the display prompts and press it again to confirm that you want the extra dose.

You should contact your prescribing specialist if 5 or more extra doses are required in a 24-hour period. Your prescribing specialist will decide if your medication dose needs to be adjusted.







Getting ready to use your VYALEV

Gather your supplies



Your items may look different to the ones shown here.

Always wash your hands with soap and water and dry them with a paper towel. Also, make sure the surface you are working on is clean. This will help to avoid contamination.

Gather all the items you need to start your infusion. You can lay out each item on your Step-by-step Infusion Guide before you begin, to make sure you have everything you need.

Ensuring that aseptic technique is used throughout the set up and administration of your treatment can help to prevent adverse infusion site reactions and infections.

^{*}Items not provided.

Inspect each item for damage and expiration



This includes your solution vial, vial adapter and syringe. Do not use any items if they are expired or the sterile packaging has been damaged.

Make sure the solution is at room temperature

If your solution vial was refrigerated prior to use, allow it to sit at room temperature out of direct sunlight for 30 minutes. Do not heat your solution in any way other than letting it warm at room temperature in the vial.

Inspect the solution

The colour of the solution may vary, but this has no impact on quality. It may vary from colourless to yellow to brown and may have a purple or red tint. It may become darker while it is in your syringe.

Check the solution to make sure there are no particles and it isn't cloudy.





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



Never dilute the solution or fill your syringe with anything other than VYALEV.

Attaching the vial to the vial adapter



Find a well-lit area and a flat work surface like a table. To minimise the risk of infection, ensure your work surface is clean.



Wash your hands

Wash your hands with soap and water and dry them.



Prepare the solution vial

Remove the solution vial cap to expose the rubber vial stopper.



Wipe the top of the vial stopper with an alcohol pad and allow to dry before attaching to the vial adapter.



Prepare the syringe

- Get a new syringe and remove it from its packaging.
- Push the rubber plunger all the way in to get rid of air



Attach the vial adapter* to the solution vial

Remove the cover from the vial adapter plastic packaging.



Centre the vial adapter on top of the vial and push down until it snaps into place.



Remove the plastic packaging and discard.

*Your vial adapter may look different to the one shown here. The instructions are only general in guidance. Please refer to the Instructions for Use included with the product for further details.



Do not let the tip of any disposable component come into contact with any unclean surfaces. If this happens, discard the item and get a new one.

Transferring your medicine from the vial to the syringe



Attach the syringe to the vial adapter

While holding the vial adapter firmly, attach the syringe by pushing and then screwing it into place, making sure not to overtighten.



Hold the syringe vertically, with the solution vial above the syringe

It is important to hold the syringe pointing straight up.



Withdraw the full contents of the vial into the syringe

While holding the syringe firmly in one hand, slowly pull the plunger rod down with your other hand to withdraw the full contents of the vial into the syringe to the 12 mL mark, or until you see air (head space) at the tip of the syringe.

Always withdraw the entire contents of the solution vial into the syringe.



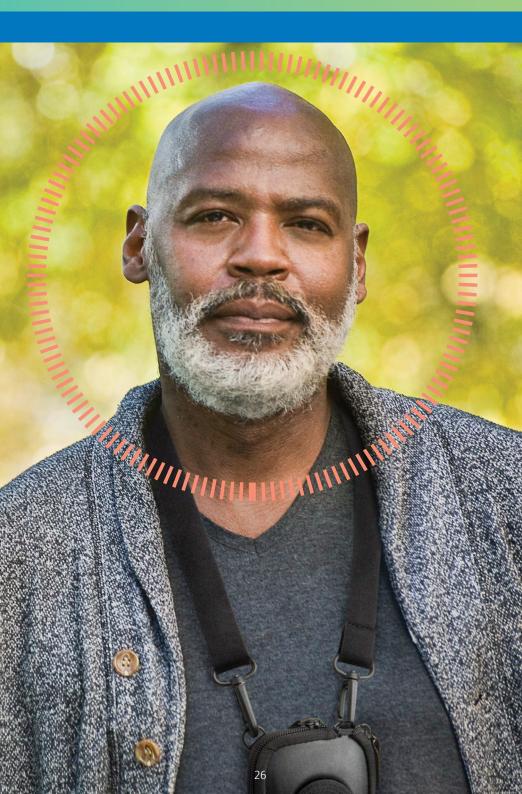


Inspect the syringe for air bubbles

Large air bubbles in the syringe must be removed as they can affect dosing accuracy. Small air bubbles are fine, and air (head space) at the tip of the syringe is expected.

If you only see small air bubbles or don't see any air bubbles, you can skip to step 10. If you see large air bubbles, continue to step 9.



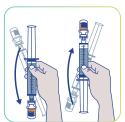


Removing air from the syringe



Rotate the syringe to gather air bubbles into a single bubble

With the solution vial still attached, slowly and gently rotate your syringe and tilt it back and forth.



If there are still air bubbles, gather them by gently rotating the syringe and attached vial end over end. When the large air bubbles are gathered into a single air bubble, continue with the next step.

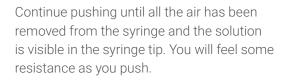


Do not shake or tap the syringe to remove air bubbles.



Push air out of the syringe

With the solution vial still attached, point your syringe upward. Slowly push the air out of the syringe and into the vial.





If the syringe is tilted slightly, you may see a small air bubble in the corner. This is OK.

Please refer to the VYALEV Instructions for Use for detailed steps on how to remove air bubbles from the syringe.



Disconnecting your syringe from the vial



Once the air has been removed from the syringe, invert the syringe and vial

Set the solution vial down on your clean, flat surface.



Disconnect the syringe from the vial adapter

Hold the vial adapter firmly with one hand and the barrel of the syringe with the other. Then unscrew the syringe from the vial adapter.

Make sure not to push against the plunger, or the solution will leak.

Place the syringe on a clean, dry surface and dispose of the vial

The used solution vials with the vial adapters still attached should be disposed of in a disposable sharps container. **Never** reuse the syringe, vial or vial adapter, even if there is solution left.

To minimise the risk of infections, do not let the tip of any disposable component come into contact with any unclean surfaces. If this happens, discard the item and get a new one.

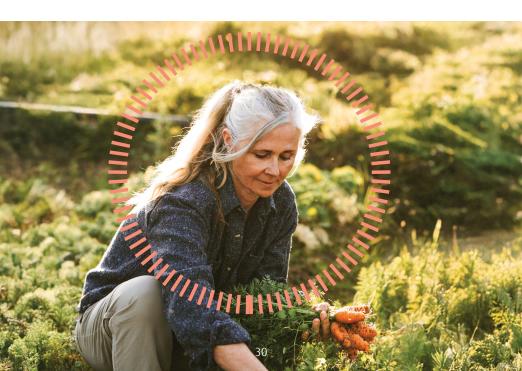
Connecting your tubing to the filled syringe

With your syringe full of solution, you are now ready to connect it to the infusion set tubing. Make sure your pump is close by, has a fully charged battery installed and is ready for use.



Remove the infusion set tubing* from the packaging

*Your infusion set tubing may look different to the one shown here. The instructions are only general in guidance. Please refer to the Instructions for Use included with the product for further details.





Attach the end of the infusion set tubing* to the new, filled syringe

Screw the end of the infusion set tubing onto the end of the syringe by turning it clockwise. Make sure it is secure but do not overtighten.

Note: The cannula and tubing must be changed at regular intervals, as per the instructions from your prescribing specialist.



Lay the other end of the tubing with the site connector on a clean paper towel while attaching the tubing to the syringe.

To minimise the risk of infections, do not let the tip of any disposable component come into contact with any unclean surfaces. If this happens, discard the item and get a new one.

^{*}Your infusion set tubing may look different to the one shown here. The instructions are only general in guidance. Please refer to the Instructions for Use included with the product for further details.

Preparing your pump



Return to your pump display and turn it on

Press any button on the front of the pump device.

Press the '**MENU**' button to display the pump menu options.



Use the arrow keys to highlight the 'Insert Syringe' option

Press 'SELECT' to choose the option to 'Insert Syringe'.

Note: The pump display will have an 'Insert Syringe' menu option when the pump does not detect that a syringe has been inserted.



Follow the instructions on the display.



Slide the lid latch to release the lock

Open your pump lid.



Place the syringe into the pump

- Place the syringe into the pump groove with the syringe flanges in the syringe flange grooves.
 Be sure the syringe tip and infusion set tubing pass cleanly through the opening of the base.
- The syringe should fit into the pump groove with little to no resistance. If the syringe does not fit inside the pump grooves, check to see if the syringe plunger has been moved to the correct position and air has been removed.
- If there is still air in the syringe tip, make sure the tubing is not connected to the cannula, then carefully push out the remaining air, making sure not to push out any of the solution.

20 Close the pump lid and confirm insertion



After making sure the syringe is correctly placed, close the pump lid until it snaps shut.



Confirm that the new syringe has been inserted by pressing the 'YES' button.



Pause to allow the pump to prepare the new syringe for use.

Priming your infusion set tubing

Priming means that the pump pushes your medicine from the syringe through the infusion set tubing to remove air in the line.



Prepare to prime the infusion set*

 Remove the protective white plastic cap from the end of the site connector. Keep the cap clean and store it for later use.

*Your infusion set may look different to the one shown here. The instructions are only general in guidance. Please refer to the Instructions for Use included with the product for further details.



Lay the needle end of your infusion set tubing on a clean paper towel so that drops will not fall onto any part of the connector.



Return to your pump display to start the priming process

- Your pump will display,
 'Do you need to prime?'
 Press 'YES'.
- Pressing 'NO' will return you to the 'Start Pump' screen.
- If you need to prime and are not seeing this screen, select 'Change Supplies' from the main menu and then 'Prime Infusion Line'.



Make sure the site connector end of the tubing is not connected to the cannula and press 'CONFIRM'.

Priming your infusion set tubing (cont.)



Prime the infusion set

- Hold your pump inverted, at a 90-degree angle, with the syringe tip straight up.
- The display will rotate so that you can read it when the pump is held this way.
- Press 'PRIME'.
- Each time you press 'PRIME', your pump will push a pulse of solution through your tubing and stop.

The pump must be pointing straight up and not tilted or the prime option will not appear on the display.





Look for a drop of solution

- Making sure the site connector is lying flat on a clean paper towel, continue to press 'PRIME' until you see a drop of solution on the paper towel.
- It may take several seconds for the drop to appear.



Press 'CONFIRM' when you see a drop of medicine on the site connector.



- Press 'YES' to confirm the appearance of the drop.
- Pressing 'NO' will bring you to the previous screen, allowing you to continue priming the pump until a drop appears.

Priming your infusion set tubing (cont.)

Prepare to attach your tubing to your cannula



Return the pump to its original orientation and place it flat on the table



Wait at least 60 seconds to ensure that the solution has stopped dripping from the site connector

 Hold the site connector flat on the paper towel for at least one minute to make sure the solution has stopped dripping from the end.

Note: Ensure that the site connector remains on the clean paper towel while priming.

 After one minute, without lifting the site connector, tap it once near the tubing with your finger so that any remaining drops break free from the tip.

Note: Some infusion sets come with protective caps, allowing you to recap the site connector and recap the cannula until it is time to connect them.

Once the infusion set tubing has been primed, it is time to attach the cannula to your body.

Before attaching the connector to the cannula, make sure it is free of drops or it may be difficult to detach from the cannula later.



Choosing an infusion site

Your infusion site should be on your belly, unless otherwise instructed by your prescribing specialist

Keep at least 5 cm away from the site of:

- Your belly button
- Any areas of scarred or hardened tissue or stretch marks
- Skin folds or creases where the body naturally bends (e.g. while sitting or exercising)
- Areas where clothing might cause irritation (e.g. near the belt line)

Choose a new infusion site every time you change your infusion set

Your new infusion site needs to be at least 2.5 cm away from your previous one, and 5 cm away from your belly button.

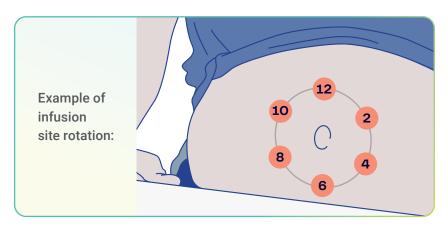
Changing your infusion site is important because it helps your skin stay healthy and your medicine enter your body correctly. Once you have used an infusion site, try not to use it again for at least 12 days.

How to rotate your infusion site

You should always follow aseptic (sterile) techniques while using VYALEV and regularly change the infusion site (at least every third day), using a new infusion set.

You may need to change the infusion site more often than every third day, if you notice any skin changes at the infusion site, such as redness, warmth, swelling, pain, and discolouration when you apply pressure to it.

Call your prescribing specialist straight away if you experience any of these changes or any other skin changes at the infusion site that worry you.





Tip: To remember your previous sites, you can write down the date and location of your infusion site. You can also use the **Infusion Site Tracker** to help you remember.

Attaching the cannula to your body



Remember, it's important to keep your hands and work surfaces clean before administering VYALEV.



Prepare your infusion site

- Select the desired infusion site on your belly. In some cases, your prescribing specialist may recommend inserting your cannula into another part of your body instead of your belly.
- Wipe the infusion site with an alcohol pad.
- Let the infusion site dry for at least 1 minute.

It is important to allow your infusion site to dry fully, or else the adhesive liner of the cannula may not stick to the skin.



Prepare your insertion device*

Carefully remove the paper from the adhesive on the bottom of your insertion device, making sure not to touch the sticky adhesive pad.

Next, remove the insertion device clear plastic safeguard near the red button by gently squeezing it on the sides and pulling it straight out.

*Your insertion device may look different to the one shown here. The instructions are only general in guidance. Please refer to the Instructions for Use included with the product for further details.



Some infusion sets come with protective caps, allowing you to recap the site connector and recap the cannula until it is time to connect them.

Attaching the cannula to your body (cont.)



Insert your cannula*

- Position the insertion device on the skin and press the red activation button completely down to insert the infusion set.
- The insertion is complete when the insertion device is released from the cannula housing with adhesive tape.
- Press on the adhesive tape around the cannula to ensure that it sticks to your skin.

Note: After the cannula is attached, you should check it regularly to ensure that there is no fluid leaking out on the skin. If the adhesive liner becomes loose, replace the cannula as this may mean that the cannula is not completely inserted under the skin.

^{*}Your cannula may look different to the one shown here. The instructions are only general in guidance. Please refer to the Instructions for Use included with the product for further details.



Connect your infusion set tubing to your cannula*

- Push the site connector at the end of your infusion set tubing into your cannula.
 You should hear a 'click' to confirm.
- Frequently check the insertion site to ensure that the soft cannula remains in place and that the site is not irritated.



When the infusion set tubing is connected to the body, DO NOT leave the infusion set tubing hanging loose because it could accidentally catch on objects, possibly resulting in the cannula becoming detached from the infusion site.

Your infusion set (both the cannula and tubing) should be changed and the infusion site rotated at least every 3 days. You may need to change the infusion site more often than every third day, if you notice any skin changes. See pages 40-41 for more details.

^{*}Your infusion set and cannula may look different to the ones shown here. The instructions are only general in guidance. Please refer to the Instructions for Use included with the products for further details.

Starting your infusion

Go back to your pump to begin your infusion

The final step is making sure your pump delivers your infusion into your body.



Turn on the pump display screen by pressing any button. Press '**MENU**' to display the pump menu options.

Always perform the following checks before starting an infusion:

- Confirm that the infusion set tubing is correctly connected to the syringe.
- Confirm that the infusion line has no kinks or other blockage.



Confirm that the infusion set tubing is connected to your cannula

Select 'CONTINUE'.



Start your pump for either a loading dose or continuous infusion

Choose the '**Start Pump**' menu option and press '**SELECT**'.



If you have not used your pump for more than 3 hours, your display will prompt you to 'Start a Loading Dose'. Otherwise, it will ask you to 'Start Pump' for a continuous infusion.

Select 'YES'

Your pump display will return to the status screen.



You should see the green 'RUNNING' notification and dot on the upper right corner of the display, showing that it is working.

Note: The pump will display the time remaining until the syringe is empty at the current rate, OR the time until the VYALEV remaining in the syringe should be discarded and replaced with a new syringe.



Contact an AbbVie Care nurse consultant if you are having difficulties with setting up the delivery system, managing the pump or administering the VYALEV medicine.





Support is available

This section provides guidance for situations that may arise when you are using the pump. In all cases, if you are unable to correct the issue, or if you do not understand the issue, contact your prescribing specialist.

Frequently asked questions

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

- If the syringe does not fit into the pump, it means either the syringe plunger rod pusher has not retracted or the air is not fully removed.
- If the syringe plunger rod pusher isn't fully retracted, 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.
- If the syringe does not fit into the pump with a fully retracted syringe plunger rod because there is still air in the syringe tip, re-attach the syringe to the vial adapter that is still attached to the vial.
- With the vial and syringe pointed upward, slowly push all remaining air and a small amount of solution back into the vial. Then re-attach the infusion set tubing and try again.
- After the remaining air has been removed from the syringe, try to load the syringe again.

What if I accidentally indicate tubing is primed, but I need to continue to prime?

Go to the 'Change Supplies' menu option on the pump, then follow the instructions to prime the infusion set tubing.

What do I do if I need to change only my infusion set tubing and not the cannula?

The procedure is similar to that for changing the entire infusion set, except that you must disconnect the infusion set tubing from the cannula, since you are not replacing the cannula.

- 1. Stop the pump.
- 2. Disconnect the old infusion set tubing from the syringe and cannula.
- **3.** Discard the old tubing.

- **4.** Connect the new tubing to the syringe.
- **5.** Prime the tubing (navigate to "Change Supplies" and select option "Prime Infusion Line").
- 6. Wait 60 seconds and tap away residual drips.
- 7. Connect primed tubing to the cannula.
- 8. Start the pump.

What if I cannot loosen the tubing from syringe during syringe placement?

Sometimes the tubing connector is overtightened and/or sticky when attached to the syringe and it is difficult to remove. Try holding a warm, damp cloth in your hand to help protect your fingers from the sharp edges of the connector and try to unscrew it.

If that does not work right away, let the dampness of the cloth soak in and try again. If you are still unable to loosen the tubing from the syringe, you will need to replace your infusion set.

Note: Do not use a tool to loosen the tubing connector because it could damage the plastic part of the connector.

What if I am having trouble transferring VYALEV from the vial to the syringe?

Try the following suggestions:

- Ensure that the vial adapter spike is centred on the rubber stopper on the top of the solution vial before you apply a downward force.
- Press vertically downward until the vial adapter snaps snugly into place onto the vial.

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

If a fully charged battery no longer enables use for at least 24 hours under normal use (18°C to 28°C), you may need a replacement battery.

When the pump is operated at temperatures below 18°C or above 28°C, the battery will have reduced capacity.

Only use a fully charged battery provided by the VYAFUSER® Pump supplier.

Support is available (cont.)

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

First, confirm that the fully charged battery is fully inserted and that the metal contacts on the battery line up with the metal contacts in the pump (refer to your VYAFUSER® Pump IFU).

If the battery is properly inserted and the pump isn't powering on, remove the battery and inspect the contacts on the battery and pump. If there is contaminant or something else blocking contact between the battery and pump contacts, attempt to remove it. If the contacts appear to require cleaning, follow the procedure described below.

Instructions for cleaning battery contacts (if needed):

- Ensure the battery is removed.
- Dip the cotton swab in isopropyl alcohol (no other cleaning agent is acceptable).
- Depress the cotton swab against the inside of the container to remove most of the alcohol.
- Wipe back-and-forth with the swab against the contaminant on either the battery contact or pump contacts.
- Allow the contacts to fully dry before inserting battery.

If the battery is properly seated and you've attempted to remove any visible contaminant and the pump is still not powering on, contact your prescribing specialist.

What should I do if the pump screen is blank or does not respond to any of my button pushes?

If the pump is not responsive or the display screen remains blank after button pushes, replace the battery with a fully charged battery. If the pump still does not respond, remove the battery and wait for 10 minutes. After 10 minutes, insert the fully charged battery. If the pump still does not respond, contact your prescribing specialist.

What should I do if my cannula becomes detached from my body after I have been using it?

If the cannula becomes loose or detached from the body, you will need to replace the entire infusion set, including the tubing and the cannula. Refer to your VYAFUSER® Pump IFU.

What if I cannot remove the site connector from the cannula during temporary disconnect?

Apply a warm, soaking wet, cloth to the site connector for at least
 2 minutes (to dissolve any dried VYALEV that may be in the connector).

Note: it may help to gently squeeze the washcloth and/or gently rub the site connector in a circular motion a few times to help the water penetrate the connector.

- Attempt to detach the site connector from the cannula and lay it flat on a clean paper towel. Ensure the site connector needle is exposed so that you can inspect for a drop of VYALEV. Tap the site connector with your finger so that any drops break free from the needle tip.
- If you are not able to detach the site connector, re-soak the cloth and reapply it to the site connector for another 2 minutes. Repeat this step as many times as necessary until the site connector can be detached from the cannula.

Note: after you have disconnected the site connector, there may still be some dried VYALEV on the connector which may make it difficult to open on subsequent attempts.

 If you are unable to detach the site connector from the cannula after multiple attempts, you will need to remove and discard the cannula and infusion set tubing.

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

If tubing is leaking where it is connected to the syringe, ensure the connection is tight enough and secured. If the tubing is damaged or blocked, or if it is leaking from the tubing or cannula, replace the infusion set, including the tubing and cannula. Refer to your VYAFUSER® Pump IFU.

Support is available (cont.)

What should I do if my pump gets wet?

If the pump gets wet, dry it off with a towel. If you accidentally drop the pump and it is submerged, call your prescribing specialist.

What should I do if I spill VYALEV?

If you spill VYALEV on a table or on your skin, use a damp cloth and wipe it off. If you spill it on your clothing, you can blot it dry or let it dry on its own. Or you can remove the clothing and wash it using water and laundry detergent.

What if I need to stop using the pump for an extended period of time?

Don't stop using VYALEV without first speaking to your prescribing specialist. If you need to stop using the pump and want to power it off completely, stop the pump, remove the battery, and replace the battery cover. Also, discuss your back-up treatment option with your prescribing specialist.



A helpful checklist

The more you use VYALEV, the more seamlessly your treatment will integrate into your daily routine.

Here is a checklist of the key steps needed to administer your VYALEV treatment:

- Gather all your supplies and inspect all items.
- Wash your hands and clean all work surfaces.
- Install the battery.
- Fill the syringe with VYALEV solution.
- Manually remove any air bubbles and remove air from the syringe.
- Prepare your syringe and place it in your pump.
- Prime your infusion set tubing.
- Attach the cannula to your body at a new location.
- Attach the infusion set tubing to your cannula.
- Start your infusion.

Some infusion sets come with protective caps, allowing you to recap the site connector and recap the cannula until it is time to connect them.

VYALEV has both benefits and risks. Always use VYALEV according to your prescribing specialist's advice. For more information about your VYALEV medicine and its delivery system, talk to your prescribing specialist and refer to the Instructions for Use and Consumer Medicine Information, available at abbv.ie/au-vylv-cmi or from your pharmacist.

