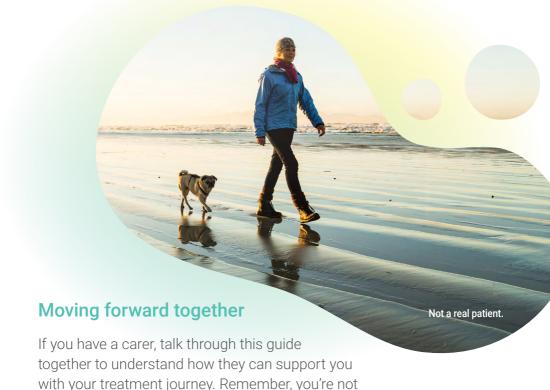


This booklet is only intended for people prescribed VYALEV for advanced Parkinson's Disease and their carers. The information provided does not replace the advice of your prescribing specialist or the information in the VYALEV Consumer Medicine Information (CMI). The CMI is available from your pharmacist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

Your healthcare 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.

Starting your VYALEV treatment journey

Living with Parkinson's disease (PD) and navigating your treatment may at times feel overwhelming. This booklet will guide you through VYALEV and its supporting items. It will cover topics such as living with PD, important safety information, tips for infusion site care, and the additional support available to you.



alone and there is support available.

Contents

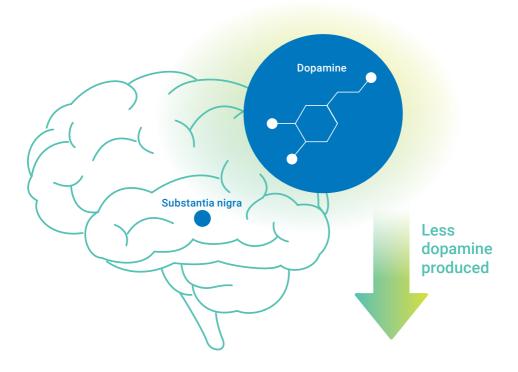
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About Parkinson's disease

What is PD?

Parkinson's disease (PD) is a movement disorder of the nervous system. It is a condition that affects nerve cells in a specific part of the brain called the **substantia nigra**.

These nerve cells are responsible for producing dopamine, which plays a vital role in smooth, controlled body movements. As these nerve cells weaken, become damaged, or die, this leads to less dopamine being produced causing symptoms of PD to appear.



What are the symptoms of PD?

Symptoms of PD generally develop slowly over time and may be different from person to person. People living with PD may experience motor symptoms (movement-related):



Motor symptoms:

- Tremor
- Stiffness
- Slow movement
- Freezing
- Impaired balance and coordination, sometimes leading to falls

People living with PD may also experience non-motor symptoms (not related to movement), such as:



Non-motor symptoms:

- Depression
- Anxiety
- Apathy (lack of emotion)
- Constipation
- Sleep disorders

- Loss of sense of smell
- Cognitive impairments
- Communication difficulties
- Swallowing difficulties

It's important to recognise that PD can have an impact on your quality of life. Let your care team know about any symptoms you are experiencing – they are here to help.





ON time is when your PD medication is working well and PD symptoms are controlled at their best, while **OFF time** is when PD medication is no longer working well and symptoms return. Your care team may refer to your medication and management of PD symptoms using these terms.

About VYALEV

Getting to know VYALEV

What is VYALEV?

VYALEV is a medicine containing two active ingredients, foslevodopa and foscarbidopa. In the body, foslevodopa and foscarbidopa are made into levodopa and carbidopa, respectively. VYALEV is used to treat advanced PD in people who meet the prescribing criteria listed in the CMI, helping to gain control over movements and posture.



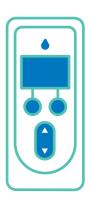
What is the VYAFUSER® Pump?

Your VYALEV medicine is administered under the skin (subcutaneously), most frequently on the abdomen (belly). This is done using a small, flexible plastic channel connected to the VYAFUSER® Pump that continuously gives you the medicine 24 hours a day. The Pump Instructions for Use can be found in your product packaging.



Never turn off your pump while in use





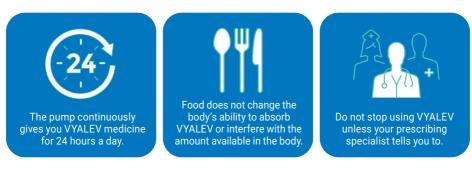
Size: 170 x 76 x 33 mm

Weight: 285 g (including battery)

How does VYALEV work?

VYALEV, comprising of foslevodopa and foscarbidopa, are made into levodopa and carbidopa, respectively.

- Once in the body, levodopa is made into a chemical called dopamine, which plays an important role in smooth, controlled body movements.
 PD occurs when the nerve cells in the brain don't produce enough dopamine, so treatment with foslevodopa helps to increase the amount of dopamine in the brain.
- Carbidopa helps to improve the effect of levodopa by preventing the breakdown of levodopa in the bloodstream, so more levodopa can enter the brain (where it is needed). Carbidopa also reduces the side effects of levodopa.



You may need to reload the pump with a new syringe within a 24-hour period to make sure you have enough of your VYALEV medicine circulating in your system to control your symptoms. Your prescribing specialist will determine your VYALEV dose based on your individual needs.

Follow all the instructions given to you by your prescribing specialist and talk to them if you have questions or concerns about your treatment or symptoms. Do not stop using VYALEV suddenly or reduce the dose without checking with your prescribing specialist.

About VYALEV

VYALEV and its supporting items



Solution vial

Each VYALEV carton contains 7 glass vials, and each vial contains 10 mL of VYALEV medicine



Vial adapter*

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

Your vial adapter may look different to the one shown here.



Syringe*

Used to draw the VYALEV medicine from the vial.



VYAFUSER® Pump*

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





Tubing

Connects your syringe in the pump to the infusion site to deliver your medicine.



Insertion device and cannula

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

Your infusion set may look different to the one shown here.

^{*}Each item listed above has an individual sponsor and is not manufactured by AbbVie.



Rechargeable batteries*

Used as the power source for operating your pump.

Note: You will need to change your battery at least once a day. Your pump comes with two rechargeable batteries.



Battery charger and adapter*



Used to charge one battery while the other is in use.

Australian adapter not shown. Your pump adapter may look different to the one shown here.

Paper towels[†]

to help to keep a clean surface for administering VYALEV



†Items are not provided.

Disposable sharps container

Used to dispose of any used medical items. Learn more about safe disposal of VYALEV on page 24.



Alcohol pads

to help clean the infusion site on your skin and keep items sterile.



Your VYALEV treatment also includes a carrying accessory to help you wear the pump on your body while on the move. Details about the carrying accessory can be found on page 20.

If you have any questions about your PD symptoms, contact your prescribing specialist. If you have any questions about how to use VYALEV and its supporting items, visit our website vyalev.com.au (use the access code: connect) or contact an AbbVie Care nurse consultant at 1800 230 608.

Using VYALEV

Before starting VYALEV



Do not use VYALEV if you:

- Are allergic to foslevodopa, foscarbidopa, levodopa, carbidopa or any of the ingredients listed in section 7 of the Consumer Medicine Information.
- Have a sudden fluid build-up inside the eye causing very high pressure (narrow angle glaucoma).
- Have had severe heart conditions (including stroke or heart attack, blocked blood vessels in your heart or an uneven heartbeat).
- Have any condition that affects the adrenal glands, such as a tumour on the adrenal gland called pheochromocytoma, or a condition called Cushing's syndrome.
- Have an over-active thyroid (hyper-thyroidism).
- Are taking antidepressants such as moclobemide, phenelzine, tranylcypromine.
- Have or have had melanoma, or if you have skin marks or sores that have not been checked by a doctor.

Speak with your prescribing specialist if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to do so. Do not use VYALEV if you are breastfeeding.



Tell your prescribing specialist if you:

- · Have had any heart conditions.
- · Have problems with your liver or kidneys.
- · Have a lung problem, such as asthma.
- · Have an eye problem called wide-angle glaucoma.
- Have, or have had, depression (low mood, a feeling of worthlessness), thoughts about self-harm or other mental health issues
- Have ever had a stomach ulcer.
- Have a condition affecting the endocrine glands (including the thyroid, adrenal glands or pancreas).
- · Have ever had fits (convulsions).
- Are on a controlled sodium diet, as VYALEV contains 42.4 mg sodium/mL.
- Take any medicines for any other condition.

Using VYALEV

VYALEV and other medicines

Some medicines may interfere with VYALEV and affect how it works. Let your prescribing specialist know if you are taking, have recently taken or might take any other medicines before starting your VYALEV treatment, including those obtained without a prescription, such as vitamins and supplements.

Check with your prescribing specialist before you use VYALEV if you are taking or have recently taken (in the last 2 weeks), any medicine to treat depression. There are certain types of antidepressants that **cannot** be taken with VYALEV, such as moclobemide, phenylzine and tranylcypromine.

Some medicines that may interfere with VYALEV include:

- entacapone (sometimes added to therapy to reduce Parkinson's symptoms for a longer time).
- other medicines used to treat Parkinson's disease (e.g. pramipexole, ropinirole and rotigotine).
- amantadine (used to treat certain viral infections).
- some medicine used to treat certain mental and emotional conditions (e.g. chlorpromazine, thioridazine, haloperidol, risperidone).
- some medicines used to treat nausea or vomiting (e.g. metoclopramide).
- some medicines that work in the brain used to treat anxiety, and to relax muscles (e.g. diazepam, clonazepam).

- isoniazid (used to treat tuberculosis).
- phenytoin (used to treat convulsions or fits).
- papaverine (used to increase blood flow, and to treat problems with the stomach and gall bladder).



Certain medicines used to treat high blood pressure (such as anti-hypertensives) may make you feel dizzy when you get up from a chair or bed. VYALEV can make these dizzy feelings worse. Slowly moving from a lying to a standing position may make you feel less dizzy.

Check with your prescribing specialist or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VYALEV. Also, remind any doctor, dentist or pharmacist you visit that you are using VYALEV.

Using VYALEV

Using the right amount of VYALEV

How much to use

- Your VYALEV dose is calculated by your prescribing specialist based on your individual needs.
- Usually, a steady dose of hourly infusion is given.
 If needed, you may have extra doses or your hourly infusion rate may need to be adjusted this will be decided by your prescribing specialist.



- If 5 or more extra doses are required in a 24-hour period, contact your prescribing specialist so they can decide if your medication dose needs to be adjusted.
- The pump continuously gives you the medicine for 24 hours daily.
 You may need to reload the pump with a new syringe within a
 24-hour period to make sure you have enough medicine in your blood to control your symptoms.
- Follow all the instructions given to you and continue to use VYALEV unless your prescribing specialist tells you to stop.

If you use more than you should

If you think that you have used too much VYALEV, you may need urgent medical attention. Immediately contact your prescribing specialist or the Poisons Information Centre (13 11 26) for advice or go to the Emergency Department at your nearest hospital, even if you are not experiencing any signs of discomfort or poisoning. Take the medicine carton with you.



If you forget to use VYALEV

The vial(s) should be changed at the same time each day. If you forget to resume VYALEV, start your pump as soon as possible.



- For interruptions longer than 1 hour, make sure to change your infusion set (tubing, insertion device and cannula) and rotate to a different infusion site before resuming infusion.
- For interruptions longer than 3 hours, you may need to also self-administer a loading dose to quickly re-establish your symptom control. You can find detailed instructions on loading dose in the Administration Guide and the VYAFUSER® Pump Instructions for Use.

Do not suddenly stop using VYALEV without first discussing with your prescribing specialist.

Using VYALEV

What you should know while using VYALEV



Call your prescribing specialist straight away if:

- you have any problems with the pump including if you are finding it difficult to manage.
- your family or carer notices you are developing urges or cravings to behave in ways that are unusual for you, or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called 'impulse control disorders' and can include addictive gambling, excessive eating or spending and abnormally high sex drive or an increase in sexual thoughts or feelings.
- your Parkinson's disease symptoms get worse or it is harder to move than usual.
- you become pregnant while using VYALEV.

Refer to page 28 to learn more about VYALEV Safety Information and when it may be necessary to call your prescribing specialist right away regarding side effects.

Remind any doctor, dentist or pharmacist you visit that you are using VYALEV.



Things you should not do:

 Do not stop using VYALEV or lower your dose suddenly unless your prescribing specialist tells you to. In such a case, your prescribing specialist may need to adjust your other medicines to control your Parkinson's symptoms, especially levodopa, to avoid Neuroleptic Malignant Syndrome (a rare condition with symptoms including muscle stiffness, agitation and confusion, coma, increases and decreases in your blood pressure, sweating, palpitations, and fever).

Be careful before you drive or use any machines or tools until you know how VYALEV affects you.



VYALEV may cause you to feel dizzy, lightheaded, or sleepy and may cause your vision to be blurred.



Using VYALEV

Looking after your medicine



How to store VYALEV

Follow the instructions in the carton on how to take care of your medicine properly.

- Keep VYALEV in the refrigerator (at 2°C to 8°C) until needed.
 Do not freeze.
- Vials that are for use beyond 28 days should be stored and transported refrigerated (at 2°C to 8°C).
- VYALEV solution can be stored at room temperature up to 30°C for up to 28 days. It is good practice to keep just one carton of VYALEV solution at room temperature at a time.
- · Keep VYALEV where young children cannot reach it.
- Once the medicine has been stored at room temperature, do not return the medicine to the refrigerator. You can record the date when you remove the medicine from the refrigerator on the carton.
- Discard the VYALEV solution if it has been stored at room temperature (up to 30°C) for longer than 28 days.
- Discard the syringe, and any unused medicine in the syringe, after VYALEV has been in the syringe for 24 hours.
- Do not use VYALEV after the expiry date.

Refer to page 24 to learn about the correct and safe disposal of VYALEV and its supporting items.

Living with VYALEV

Continuing with your daily activities

You can use VYALEV as you continue with your daily activities. Establishing a routine that incorporates your treatment can help to streamline your day-to-day planning, making it easier for you to go about your daily activities.



Bathing, showering or engaging in water activities

- VYALEV can be interrupted for brief periods of time, such as when taking a shower.
- Your pump cannot get wet, so make sure to disconnect it before you bathe, shower or engage in water activities.
- Do not submerge your pump in water.



Disconnecting or reconnecting to your pump

- Make sure to change your infusion set (tubing, insertion device and cannula) and rotate to a different infusion site if you interrupt the infusion for longer than 1 hour.
- For interruptions longer than 3 hours, you may need to also self-administer a loading dose to quickly re-establish your symptom control.



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. Refer to the VYAFUSER® Pump Instructions for Use leaflet for more information.

It may be helpful to discuss with your prescribing specialist about having a current script for your oral medication. This can serve as a backup in case your VYALEV treatment is interrupted.

Living with VYALEV

Using VYALEV on the go

Carrying accessory

The different pieces of the carrying accessory allow you to wear your device with flexibility:



Case* holds your pump

*It is not designed to keep the pump dry or protect the pump from water droplets in a shower, rain or from other liquid spills.



Belts allow for customised fit across your waist or chest



Strap has a comfort pad for wearing on your neck or shoulder



Removable flap helps to protect your pump buttons

You can wear your carrying accessory in different ways. Choose one that works best for you:



When the syringe is in the pump and the infusion set tubing is connected to the body, the syringe **CANNOT** be no more than 20 cm above or 55 cm below the infusion site. Placing it higher or lower than indicated could impact the accuracy of medicine delivery.



- To minimise the risk of strangulation, do not use the carrying accessory in a way such that the strap or belts could wrap around your neck.
- Clean your carrying accessory as needed. Use a damp cloth with mild detergent to gently wipe any surface that requires cleaning.

Living with VYALEV

Travelling with VYALEV

Items to bring with you

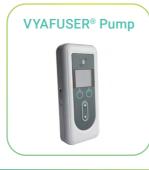
When travelling, make sure to carry additional supplies with you to manage your VYALEV treatment seamlessly while you are away. It's also a good idea to pack extra supporting items in case your plans unexpectedly change.



















Batteries, charger and adapter

Australian adapter not shown. Your pump adapter may look different to the one shown here.

Your items may look different to the ones shown here.





Paper towels



Backup oral medication (if applicable)





Transporting your solution vials

- Vials may be kept at room temperature up to 30°C for a single period of up to 28 days. Once the medicine has been stored at room temperature, do not return it to the refrigerator.
- Vials that are for use beyond 28 days should be stored and transported refrigerated (2°C to 8°C).

For more information about travelling with VYALEV, visit **vyalev.com.au** and use the access code **connect**.

Tell your healthcare team about any upcoming trips you have planned. They can help determine what is possible and make sure that you have everything you need when you leave home with your VYALEV.

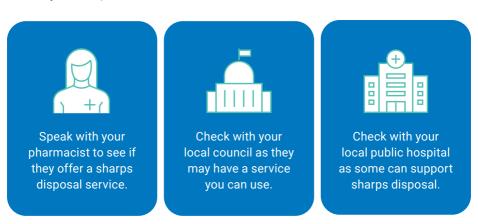
Living with VYALEV

Managing waste and sharps disposal

It is important to dispose of waste correctly and in line with your local guidelines.

- After you have administered VYALEV, place your used solution vial, syringe, vial adapter, tubing and cannula into the disposable sharps container straight away.
- Keep your disposable sharps container in a safe and secure location, out of reach and sight of children.

When your disposable container is full:



Speak with your pharmacist about sourcing a disposable sharps container.

Caring for your skin

Infusion site care

It's important to actively monitor and care for your skin to avoid any adverse infusion site reactions and infections.

When using VYALEV, it's important to:



Follow aseptic techniques

This means using sterile practices when administering VYALEV to reduce the risk of infection.

It is important that you wash your hands with soap and water and dry them, use alcohol pads to wipe the top of the solution vial, and clean the surfaces before and after an infusion.



Maintain general hygiene

Prepare your skin where you plan to insert your cannula. Clean it thoroughly with an alcohol pad prior to infusion. Make sure to let the infusion site dry for at least a minute before inserting the cannula.



Monitor for any skin changes

Monitor for any skin changes at the infusion site that could indicate infection, abscess and cellulitis. This may include redness, warmth, swelling, pain and discolouration. If this occurs, call your prescribing specialist straight away.

Caring for your skin

Infusion site care (cont.)



Infusion site rotation

Rotate your infusion site **at least every 3 days**, using a new infusion set (tubing, insertion device and cannula). You may need to change the infusion site more often than every 3 days, if you notice any of the above skin changes or if advised by your prescribing specialist.



Distance between infusion sites

Ensure your new infusion sites are **at least 2.5 cm away** from your previous sites within the last 12 days. You can use the **Infusion Site Tracker** to help you keep track of this.

Infusion site skin management

Managing your skin around the infusion site

In addition to following aseptic techniques and rotating the infusion site, here are some things you can do:



Spike ball

- A spike ball may be used to massage the skin around the infusion site for at least 10 minutes a day, for a few days after the needle is removed from the site. This may help to resolve any nodules (small lumps) that may form under your skin.
- Speak to your prescribing specialist for practical tips to support a good massage technique.



Massage

 If you don't have a spike ball, you can simply massage your skin around the infusion site softly with your hand or a hand-held massage device for at least 10 minutes a day.



Cold compress

 Applying a cold compress to the infusion site may help to reduce swelling and redness, if needed.

Speak with your pharmacist about where to source the items mentioned above. If the skin changes continue or if you are concerned, follow up with your prescribing specialist.

Important safety information

Possible side effects

Like all medicines, VYALEV may cause side effects. However, everyone is different. Some people may experience side effects and others may not.

If you do experience any side effects, most are minor and temporary. However, some side effects may need medical attention. Make sure to tell your prescribing specialist, GP, nurse or pharmacist as soon as possible if you start to feel unwell while using VYALEV. Your carer may observe symptoms and side effects that are not obvious to you, so make sure to discuss with them.



Speak to your prescribing specialist or GP if you have any of these less serious side effects and they are worrying you

Brain and nerves:

- · Headache, blurred vision
- Anxiety
- Falling
- Feeling dizzy when you stand up quickly or change positions
- Uncontrollable twitching, jerking movements or a worsening of your PD symptoms
- False beliefs (delusion)

- Feeling less sensitive to touch, tingling or numbness, burning or prickling in the hands, arms, legs or feet
- Poor bladder control or difficulty passing urine
- Feeling tired (can be sudden), weak, faint and short of breath
- Swelling in your lower legs or hands
- · Difficulty sleeping or insomnia
- Difficulty thinking, learning and remembering



Gut:

- Pain in your belly
- Decreased appetite
- Constipation
- Dry mouth
- · Nausea and vomiting
- · Weight loss

Skin:

- · Infusion site redness
- Infusion site swelling
- · Infusion site nodule or pain
- · Rashes and itching



Call your prescribing specialist or GP straight away if you notice any of these serious side effects

Skin:

Infusion site infection, abscess or cellulitis
 Infusion site infection can lead to sepsis (symptoms such as fever, rapid heart rate and rapid breathing)

Brain and nerves:

- Low mood or feeling a sense of worthlessness (depression)
- · Thoughts of self-harm
- · Feeling confused or especially nervous
- Seeing or hearing things that aren't real (hallucinations)
- Sudden uncontrolled urges

Important safety information



Go straight to the Emergency Department at your nearest hospital if you have any signs of these very serious side effects

Allergic reaction:

- Swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- Rash or hives

Neuroleptic malignant syndrome:

- Fast heartbeat and blood pressure changes
- · Fast breathing
- · Sweating and fever
- Muscle stiffness
- Losing consciousness
- · Agitation and confusion

General:

 Acute pain in eyes, headache, blurred vision, nausea and vomiting (these may be signs of narrow angle glaucoma)

Tell your prescribing specialist, GP, nurse or pharmacist if you notice anything else that may be making you feel unwell. Other side effects not listed here may occur in some people. Also, make sure you speak to your prescribing specialist or pharmacist before you decide to stop taking any of your medicines.

For more details on possible side effects, review the Consumer Medicine Information available online at abbv.ie/au-vylv-cmi, by scanning the QR code on the back of this booklet or from your pharmacist.



Support

Support available to you

Your care team

Your care team is here to help and support you through your VYALEV treatment journey.

Prescribing specialist*

- Your prescribing doctor
- Main point of contact for any questions regarding Parkinson's disease (PD) symptoms, disease progression and treatment decisions
- Responsible for your overall care and management of your condition

*This could be a neurologist, movement disorder specialist or geriatrician

Parkinson's clinic nurse*

- Works alongside your prescribing specialist to manage your PD symptoms and treatment plan
- Provides medical advice to support your overall wellbeing

*Not all clinics have a PD nurse





AbbVie Care nurse consultants

- A team of nurses accessible through AbbVie Care to complement the care of your prescribing specialist
- Help you get started on your treatment and available to support you with any questions related to VYALEV medication and delivery system*

*No medical advice

Allied health professionals

- Include a pharmacist, physiotherapist, occupational therapist, speech therapist, dietitian, social worker and psychologist
- Help you manage your PD-related symptoms and other aspects of living with PD

Your caregiver(s)

- Include your significant other, family members, friends and carers
- Help and support you with your day-to-day routine

Support



AbbVie Care is here to support you

AbbVie Care is a support program that offers a wealth of resources and tools, including tips to help you keep track of your treatment and lifestyle information. You also have access to our AbbVie Care nurse consultants to support you during your treatment journey.

An AbbVie Care nurse consultant can help you get started on your VYALEV treatment and provide support and education on the medicine, pump and supporting items. For medical advice, support on your specific treatment plan and PD symptom management, contact your prescribing specialist.

Speak with your prescribing specialist if you would like to be enrolled in AbbVie Care.



Tools and resources

There are various resources available to help you stay on track with your treatment.

Organisational tools:

- Step-by-step Infusion Guide to help make sure you have everything you need and follow the correct steps when administering VYALEV.
- **Infusion Site Tracker** to help you keep track of the location and date of your infusion site.
- Other practical tools to help you organise your medicine and supporting items.

Resources:

- Downloadable booklets and brochures
- Educational videos

To access more resources, simply:



OR



Support

Organisations and support groups

Connecting with other people in the PD community is a great way to help you feel more in control of your condition and learn how others navigate the journey. Here are some support groups in Australia:



Parkinson's NSW Online Support Groups

Participants can connect with each other to share information and inspiration about living with Parkinson's disease. For more information, contact:

supportgroups@parkinsonsnsw.org.au



Parkinson's Peer Support Groups

Parkinson's peer support offers information, social connection, hope and support through group meetings, phone calls, online communities and educational seminars. For more information, contact:

info@fightparkinsons.org.au



27forParkinson's

A group for participants to come together and share pictures and videos of their walks, tell stories about why they're walking, and encourage and connect with each other. For more information, contact:

fund raising @fight park in sons. or g. au

Links to external websites are offered for your convenience. References to any products, services or other information by trademark or otherwise is not intended to imply endorsement by AbbVie Pty Ltd. Any healthcare information provided within these sources should be discussed with your healthcare professional and does not replace their advice.

The following external organisations provide resources and information for people living with PD as well as their loved ones:



Parkinson's Australia

The national advocacy body representing people living with Parkinson's disease, their families and carers, researchers, and health professionals in the Parkinson's community.

parkinsons.org.au



Shake it Up Australia Foundation

A not-for-profit organisation established in 2011 and in partnership with The Michael J. Fox Foundation (MJFF) that promotes and funds Parkinson's disease research in Australia aimed at better treatments and ultimately a cure.

shakeitup.org.au



Fight Parkinson's

Formerly known as Parkinson's Victoria, Fight Parkinson's is a leading Australian authority providing research, education and support for people living with Parkinson's, their families and carers, and healthcare professionals.

fightparkinsons.org.au

Notes

Always speak to your prescribing specialist if you have questions about your condition or treatment. This booklet contains information that is supplementary to the Consumer Medicine Information (CMI). Please refer to the CMI before starting VYALEV treatment, available online at abbv.ie/au-vylv-cmi, by scanning the QR code or from your pharmacist.





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