

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using VYALEV?

VYALEV contains two ingredients foslevodopa and foscarbidopa. VYALEV is used to treat advanced Parkinson's disease.

For more information, see Section [1. Why am I using VYALEV?](#) in the full CMI.

2. What should I know before I use VYALEV?

Check the list of ingredients at the end of the CMI. Do not use VYALEV if you have ever had an allergic reaction to any of them.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VYALEV?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VYALEV and affect how it works, or VYALEV may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VYALEV?

- VYALEV is a solution (liquid) that goes through an infusion pump and a tube under your skin (subcutaneously).
- VYALEV dose is calculated by your doctor based on your individual needs.

More instructions can be found in Section [4. How do I use VYALEV?](#) in the full CMI.

5. What should I know while using VYALEV?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you notice any skin changes at the infusion site. You should always follow aseptic (sterile) techniques while using this medicine.• Regularly change the infusion site (at least every third day), using a new infusion set.• Tell your doctor if your Parkinson's symptoms get worse.• If you are pregnant or breast-feeding, ask your doctor for advice before using this medicine.• Remind any doctor, dentist or pharmacist you visit that you are using VYALEV.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or reduce the dose without checking with your doctor. Always follow the directions provided from your doctor.
Driving or using machines	<ul style="list-style-type: none">• Use caution when driving or operating machines.
Drinking alcohol	<ul style="list-style-type: none">• There is no information on the effects of using VYALEV with alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store VYALEV in the refrigerator at 2°C to 8°C. Do not freeze.• However, vials may be kept at room temperature up to a maximum of 30°C for a single period of up to 28 days. Once a vial has been stored at room temperature, do not return the product to the refrigerator.

For more information, see Section [5. What should I know while using VYALEV?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are pain and redness at the infusion site, uncontrollable twitching, jerking movements, hallucination, fall, anxiety, and dizziness. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VYALEV®

Active ingredient(s): foslevodopa (fos-lee-voe-'doe-pah) and foscarnidopa (fos-'kah-bee-'doe-pah)

Consumer Medicine Information (CMI)

This leaflet provides important information about using VYALEV. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VYALEV.**

Where to find information in this leaflet:

1. [Why am I using VYALEV?](#)
2. [What should I know before I use VYALEV?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use VYALEV?](#)
5. [What should I know while using VYALEV?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using VYALEV?

VYALEV contains two ingredients foslevodopa and foscarnidopa. In the body, foslevodopa and foscarnidopa are made into levodopa and carbidopa, respectively. Levodopa is then made into 'dopamine'. This adds to the dopamine already in your brain and spinal cord. Dopamine helps transfer signals between nerve cells. Too little dopamine causes Parkinson's disease signs like tremor, feeling stiff, slow movement, and problems keeping your balance. Treatment with foslevodopa increases the amount of dopamine in your body. This means it reduces these signs.

Foscarnidopa improves the effect of foslevodopa. It also reduces the side effects of foslevodopa.

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

2. What should I know before I use VYALEV?

Warnings

Do not use VYALEV if:

- you are allergic to foslevodopa, foscarnidopa, levodopa, carbidopa or any of the ingredients listed at the end of this leaflet.
- you have a sudden fluid build-up inside the eye causing very high pressure (narrow angle glaucoma).
- you have had severe heart conditions (including stroke or heart attack, blocked blood vessels in your heart or an uneven heartbeat (arrhythmia)).
- you have any condition that affects the adrenal glands, the glands responsible for releasing hormones that control heart rate, metabolism, and blood

pressure, e.g. a tumour on the adrenal gland called pheochromocytoma, or a condition called Cushing's syndrome.

- you have an over-active thyroid (hyper-thyroidism).
- you are taking antidepressants called monoamine oxidase (MAO) inhibitors such as **moclobemide, phenelzine, tranylcypromine.**
- you have or have had melanoma, or if you have skin marks or sores that have not been checked by a doctor.

Check with your doctor if you:

- have had any heart conditions.
- you 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) or you have had thoughts about suicide.
- have or have had 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 per mL.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or plan to do so. **Do not use VYALEV if you are breast-feeding.**

Children

- VYALEV is not recommended for children younger than 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VYALEV and affect how it works.

Check with your doctor 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. These can include some MAO inhibitors. Examples include moclobemide, phenelzine, tranylcypromine.

Medicines that may increase the effect of VYALEV include:

- entacapone, tolcapone, opicapone (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)

Medicines that may reduce the effect of VYALEV include:

- 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).

Medicines where VYALEV may increase their effect include:

- certain medicines used to treat high blood pressure (such as anti-hypertensives) which may make you feel dizzy when you get up from a chair or bed (orthostatic hypertension).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VYALEV.

4. How do I use VYALEV?

How much to use

- The VYALEV dose is calculated by your doctor based on your individual needs.
- Follow all the instructions given to you and continue to use VYALEV until your doctor tells you to stop.

How to use

- Your doctor or pharmacist will train you on proper use of VYALEV and the delivery system (pump, solution vial, vial adapter, syringe, infusion set, carrying accessory, rechargeable battery, and charger) prior to initiating treatment with VYALEV and as needed.
- VYALEV is a solution that is administered under your skin (called 'subcutaneous infusion') most frequently on the abdomen (choose an area at least 5 cm from the belly button) using an infusion pump.
- Rotate the infusion site and use a new infusion set (tubing and cannula) at least every 3 days. If the

infusion is interrupted for less than 1 hour, then the infusion set can remain in place for up to 3 days.

- The solution comes in a glass vial. The solution from the vial is transferred to a sterile syringe and the syringe is then placed within the pump.
- The entire contents of the vial should be transferred all at one time into a syringe for administration.
- The pump is connected via a tube for subcutaneous infusion to a cannula that is applied onto your skin.
- Administer VYALEV only with the Vyafuser Pump and infusion components (syringe, infusion set, and vial adapter) qualified for use. Follow the steps as indicated in your Patient Instructions for Use of Vyafuser Pump.

When to use VYALEV

- 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 doctor. You should contact your doctor if 5 or more extra doses are required in a 24-hour period. Your doctor will 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.

VYALEV can be interrupted for brief periods of time, such as when taking a shower. Make sure to change your infusion set (tubing 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. Do not stop using VYALEV unless a doctor tells you to.

Click on the link for the instructions on how to use VYALEV: <https://www.medsinfo.com.au/media/veivyale>

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on VYALEV.

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 and cannula) and rotate to a different infusion site before resuming infusion. For interruptions longer than 3 hours, you may need to also administer a loading dose to quickly re-establish your symptom control. Do not suddenly stop using VYALEV without discussing with your doctor.

If you use too much VYALEV

If you think that you have used too much VYALEV, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital. Take the medicine pack with you.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VYALEV?

Things you should do

Call your doctor straight away if you:

- notice any skin changes at the infusion site, such as redness, warmth, swelling, pain, and discolouration when you apply pressure to it. You should always follow aseptic (sterile) techniques while using this medicine 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, if you notice any of the above-mentioned skin changes.
- you have any problems with the pump including if you are finding it difficult to manage it.
- you, 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.
- you, your family or carer notice you are developing addiction-like symptoms leading to craving for large doses of Vyalev and other medicines used to treat Parkinson's disease.
- your Parkinson's disease symptoms get worse or it is harder to move than usual.
- you become pregnant while using VYALEV.

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 doctor tells you to. In such a case your doctor 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).

Driving or using machines

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.

Drinking alcohol

There is no information on the effects of using VYALEV with alcohol.

Looking after your medicine

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). Do not freeze.
- Vials that are for use beyond 28 days should be stored and transported refrigerated (at 2°C to 8°C).

The vials may be kept at room temperature up to a maximum of 30°C for a single period of up to 28 days (record the date when you remove the medicine from the refrigerator on the carton).

Keep it where young children cannot reach it.

When to discard your medicine

Once the medicine has been stored at room temperature, do not return the medicine to the refrigerator. Discard medicine if not used within the 28 days stored at room temperature.

Discard the syringe and any unused medicine in the syringe after the medicine has been in the syringe for 24 hours.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Bear in mind that with Parkinson's disease and its treatment, your carer may observe some symptoms more easily than you.

Less serious side effects

Less serious side effects	What to do
Skin: <ul style="list-style-type: none"> • Infusion site redness • infusion site swelling (oedema) • infusion site nodule, pain • rashes and itching Brain and nerves: <ul style="list-style-type: none"> • headache • anxiety • falling 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> feeling dizzy when you stand up quickly or change positions uncontrollable twitching, jerking movements or a worsening of your Parkinson's symptoms reduced sense of touch, tingling or numbness, burning or prickling feeling in your hands, arms, legs or feet unable to control urine (incontinence) or have difficulty passing urine feeling tired, weak (fatigue), faint swelling in your lower legs or hands caused by too much fluid feeling short of breath feeling suddenly very tired difficulty sleeping (insomnia) false beliefs (delusion) difficulty thinking, learning and remembering <p>Gut:</p> <ul style="list-style-type: none"> pain in your belly decreased appetite constipation dry mouth nausea, vomiting weight loss 	

More serious side effects

Serious side effects	What to do
<p>Skin:</p> <ul style="list-style-type: none"> Infusion site infection, abscess, cellulitis <p>- There may be a potential for germs to enter the blood and spread all over the body from infusion site infection, this is called sepsis (symptoms such as fever, rapid heart rate and rapid breathing).</p> <p>Brain and nerves:</p> <ul style="list-style-type: none"> low mood or feeling a sense of worthlessness (depression) thoughts of suicide feeling confused or especially nervous seeing or hearing things that aren't real (hallucinations) sudden uncontrolled urges. 	<p>Call your doctor straight away if you notice any of these serious side effects.</p>

Very serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, rash (hives). <p>Neuroleptic Malignant Syndrome:</p> <ul style="list-style-type: none"> agitation, confusion fast heartbeat, blood pressure changes sweating, and fever, fast breathing, muscle stiffness, losing consciousness <p>General:</p> <ul style="list-style-type: none"> Acute pain in eyes, headache, blurred vision, nausea and vomiting. These may be signs of narrow angle glaucoma. 	<p>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VYALEV contains

Active ingredient (main ingredient)	Foslevodopa (converted in the body to levodopa), and foscarbidopa (converted in the body to carbidopa).
Other ingredients (inactive ingredients)	sodium hydroxide, hydrochloric acid and water

Do not take this medicine if you are allergic to any of these ingredients.

What VYALEV looks like

VYALEV is a sterile, preservative-free, colourless to yellow to brown, clear to slightly opalescent solution in a glass vial. The solution should be free from particles and may have a purple or red tint. Variations in colour are expected and have no impact on medicine quality. The solution may become darker in colour after piercing of the vial stopper or while in the syringe.

1 mL of solution contains 240 mg foslevodopa and 12 mg foscarnidopa.

Each carton contains 7 vials of 10 mL each.

The carton includes the Australian registration number AUST R 372902.

Who distributes VYALEV

VYALEV is distributed in Australia by:

AbbVie Pty Ltd

241 O’Riordan Street

MASCOT NSW 2020

Australia

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