Package leaflet: Information for the patient

Produodopa 240 mg/ml + 12 mg/ml solution for infusion

foslevodopa and foscarbidopa

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Produodopa is and what it is used for
2. What you need to know before you use Produodopa
3. How to use Produodopa
4. Possible side effects
5. How to store Produodopa
6. Contents of the pack and other information
7. Instructions for use for Produodopa infusion using the Vyafuser pump

1. What Produodopa is and what it is used for

Produodopa contains two active ingredients, foslevodopa and foscarbidopa, and is used to treat Parkinson's disease.

How Produodopa works
- In the body, foslevodopa is 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.
- Foscarbidopa improves the effect of foslevodopa. It also reduces the side effects of foslevodopa.

2. What you need to know before you use Produodopa

Do not use Produodopa if you
- are allergic to foslevodopa, foscarbidopa, or any of the other ingredients in this medicine (listed in section 6)
- have an eye problem called 'narrow angle glaucoma'
- have severe heart problems
- have a severe uneven heartbeat (arrhythmia)
- have an acute stroke
- are taking medicines called non-selective MAO inhibitors and selective MAO-A inhibitors such as moclobemide or phenelzine. You need to stop using these medicines at least two weeks before you start taking Produodopa.
- have a tumour of the adrenal gland (pheochromocytoma)
- have hormone problems such as too much cortisol (Cushing's syndrome) or your thyroid hormone levels are too high (hyper-thyroidism)
- have ever had skin cancer, or you have any unusual moles or marks on your skin which have not been looked at by your doctor.

Do not use Produodopa if any of the above apply to you. If you are not sure, talk to your doctor before using the medicine.

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before and during the use of Produodopa if you

- ever had a heart attack, blocked blood vessels in your heart, or any other heart problems including an uneven heartbeat (arrhythmia)
- have a lung problem – such as asthma
- have ever had a hormone problem
- have ever had depression with thoughts of suicide or any other mental problems
- have an eye problem called 'wide-angle glaucoma'
- have ever had a stomach ulcer
- have ever had fits (convulsions)
- have kidney or liver disease
- are on a controlled sodium diet (see 'Produodopa contains sodium')
- have any skin changes at the infusion site such as redness, warmth, swelling, pain, or discolouration when you apply pressure to it
- have progressive weakness, pain, numbness or loss of sensation in your fingers or feet (polyneuropathy). Your doctor will check for these signs and symptoms before you start Produodopa and periodically thereafter. Tell your doctor if you already have neuropathy or a medical condition that is associated with neuropathy.

If any of the above apply to you or if you are not sure, talk to your doctor before starting Produodopa.

Tell your doctor if you notice involuntary and uncontrollable movements of your limbs, back, neck, or chin (dyskinesias) or an increase in stiffness or slowness of movements. Your daily dose may need adjustments, or the device might be obstructed.

Neuroleptic Malignant Syndrome
Do not stop using Produodopa unless your doctor tells you to. This is because suddenly stopping or lowering your Produodopa dose quickly may cause a serious problem called 'Neuroleptic Malignant Syndrome'. The signs may include

- fast heartbeat, changing blood pressure and sweating, followed by fever
- faster breathing, muscle stiffness, lower consciousness and coma
- higher levels of a protein in your blood (an enzyme called 'creatine phosphokinase'). This is measured by your doctor.

Impulse control disorders – changes in your behaviour
Tell your doctor if 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
- abnormally high sex drive or an increase in sexual thoughts or feelings.

Your doctor may need to review your treatments. They will discuss ways of managing or reducing these symptoms with you (see also section 4 'Impulse control disorders – changes in your behaviour').

Dopamine Dysregulation Syndrome
Tell your doctor if you, your family, or carer notices you are developing addiction-like symptoms leading to craving for large doses of Produodopa and other medicines used to treat Parkinson's disease.

Infusion site infections

Tell your doctor if you notice any skin changes at the infusion site, such as redness, warmth, swelling, pain, or 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 3rd day, if you notice any of the above-mentioned skin changes.

Produodopa and cancer
In the body, foscarbidopa (a component of Produodopa) is broken down into something called 'hydrazine'. It is possible that hydrazine could damage your genetic material which could lead to cancer. However, it is not known if the amount of hydrazine produced when taking a normal dose of Produodopa can cause this.

Children and adolescents
Produodopa is not recommended for children and adolescents under 18 years of age. This is because the medicine has not been studied in this age group.

Other medicines and Produodopa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines.

Talk to your doctor or pharmacist before starting Produodopa if you are taking other medicines for
- tuberculosis – such as isoniazid
- anxiety – such as benzodiazepines
- nausea or vomiting – such as metoclopramide
- high blood pressure – such as anti-hypertensives
- spasms in the blood vessels – such as papaverine
- fits (convulsions) or epilepsy – such as phenytoin
- psychiatric disease– such as anti-psychotics including phenothiazines, butyrophenones and risperidone
- Parkinson's disease – such as tolcapone, entacapone, opicapone, and amantadine
- depression – such as tricyclic antidepressants including amoxapine and trimipramine.

Tell your doctor or pharmacist if you are taking a COMT (catechol-O-methyl transferase) inhibitor as it may increase the levodopa amount in your blood. Your doctor may need to adjust the dose of either medicine.

Tell your doctor or pharmacist if you are taking medicines called sympathomimetic drugs such as - but not limited to - salbutamol, phenylephrine, isoproterenol, dobutamine to treat low blood pressure. Sympathomimetic medicines and levodopa can increase the risk of high blood pressure (hypertension) or irregular heartbeats (arrhythmia).

Tell your doctor or pharmacist if you are taking medicines known to be eliminated by an enzyme called 'CYP1A2'. Examples of such medicines include:
- caffeine (helps mental alertness)
- melatonin (helps with sleep)
- fluvoxamine, duloxetine (anti-depressants which improve mood)
- clozapine (controls schizophrenia)
- theophylline (helps with asthma)

Certain medicines (such as selegiline) that you take may lower your blood pressure, which may make you feel dizzy when you get up from a chair or bed (orthostatic hypotension). Produodopa can make these dizzy feelings worse. Slowly moving from a lying to a standing position can make you feel less dizzy.

Do not use Produodopa if you are taking

- medicines for depression called selective MAO-A inhibitors and non-selective MAO inhibitors such as moclobemide or phenelzine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Produodopa is not recommended during pregnancy or in women of childbearing potential not using contraception unless the benefits for the mother outweigh the possible risk to the unborn baby.

It is not known if Produodopa passes into breast milk. Breast feeding should be discontinued during Produodopa therapy.

Driving and using machines
Do not drive or use any tools or machines until you are sure how Produodopa affects you.
- Produodopa may make you feel very sleepy, or you may sometimes find yourself suddenly falling asleep (sleep attacks).
- Produodopa may lower your blood pressure, which can make you feel light-headed or dizzy.

Do not drive or use any tools or machines until you feel fully awake again or you no longer feel light-headed or dizzy.

Produodopa contains sodium
Talk to your doctor or pharmacist if you need 9 ml or more of Produodopa on a daily basis for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to use Produodopa

Always use this medicine exactly as your doctor, nurse, or pharmacist has told you. Check with your doctor, nurse, or pharmacist if you have questions.

How to use Produodopa
- Before you start treatment you, or your caregiver, will get training in how to handle the product and the infusion pump.
- Produodopa is a solution that is administered under your skin (called subcutaneous infusion) most frequently in the abdomen, using an infusion pump. You should avoid using the infusion pump in the 5 cm circular area around the navel.
- Your doctor or nurse will adjust the settings on the pump, so the dose fits your specific needs.
- The pump continuously gives you the medicine over 24 hours. 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.

How much medicine to use
- Always use this medicine as your doctor has instructed.
- Your doctor will decide how much Produodopa you should use and for how long. Usually, a continuous maintenance dose is given.
- If needed, you may have extra doses (an available option on your pump) to manage sudden “Off” symptoms experienced during the continuous infusion – this will be decided by your doctor.
- For interruptions longer than 3 hours, you may need to also self-administer a loading dose (an available option on your pump) prior to resuming the continuous infusion to quickly re-establish your symptom control.

Read section 7 “Instructions for Use for Produodopa infusion using the Vyafuser pump” before using Produodopa.

If you use more Produodopa than you should
If you have used more Produodopa than you should, stop the infusion immediately and talk to your doctor or go to a hospital straight away. Take the medicine pack with you. The following effects may happen

- unusual fast, slow or uneven heart beats (arrhythmia)
- low blood pressure (hypotension)

If you forget to use or stop using Produodopa
If you forget to use Produodopa, start your pump with your normal dose as soon as possible.

Produodopa 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. The loading dose option is available in your pump as set by your doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Produodopa and tell your doctor right away, if you notice any of the following serious side effects. You might need urgent medical treatment.

- angle closure glaucoma (acute pain in eyes, headache, blurred vision, nausea and vomiting).
- swelling of the face, tongue or throat which may make it difficult to swallow or breathe, or nettle type skin rash. These may be signs of a severe allergic reaction (anaphylactic reaction). Frequency not known. Cannot be estimated from available data.

Your doctor will decide if you can keep using Produodopa.

Other side effects
Tell your doctor, pharmacist, or nurse if you notice any of the following side effects.

Very common: may affect more than 1 in 10 people

- infusion site infection (infusion site cellulitis) (see section 2)
- anxiety
- seeing, hearing or feeling things that are not there (hallucination)
- depression
- infusion site reactions (redness, lump, swelling, pain)
- falling
- urinary tract infections.

Common: may affect up to 1 in 10 people

- infusion site reactions (bruising, peeling of thin layers of skin, leakage of the medicine, bleeding, inflammation, irritation, mass, bump, itching, rash)
- infusion site abscess
- decreased appetite
- confusion
- false beliefs (delusion)
- paranoia
- thoughts to end your own life (suicidal thoughts)
- problems with your ability to think, learn and remember (cognitive disorder)
- movements you make without wanting to (dyskinesia)
- muscle spasms you cannot control – affecting your eyes, head, neck and body (dystonia)
- headache

- reduced sense of touch, tingling or numbness, burning or prickling feeling in your hands, arms, legs or feet (hypoaesthesia, paraesthesia)
- progressive weakness or pain or numbness or loss of sensation in the fingers or feet (polyneuropathy)
- Parkinson's disease symptoms coming back quickly or when not expected – this is called the 'on and off phenomenon'
- suddenly falling asleep (sleep attacks), feeling very sleepy, sleep disorders
- high or low blood pressure
- feeling dizzy
- feeling dizzy when you stand up or change positions (orthostatic hypotension, postural dizziness) – this is from low blood pressure. Always change positions slowly – do not stand up quickly
- fainting
- pain in your belly (abdomen)
- constipation
- dry mouth
- feeling sick (nausea), diarrhoea, or being sick (vomiting)
- unable to control urine (incontinence)
- difficulty passing urine (retention of urine)
- lack of energy, feeling weak (fatigue)
- swelling in your lower legs or hands caused by too much fluid (oedema peripheral)
- psychotic disorder
- having too little vitamin B6 in your body
- having too little vitamin B12 in your body
- increased number of amino acids, the small parts that make proteins in the body
- increased amount of homocysteine in the blood, which helps build proteins in the body
- throat pain
- weight gain
- weight loss
- difficulty sleeping (insomnia)
- rashes, itching, increased sweating
- muscle spasms
- feeling short of breath
- feeling generally unwell
- anaemia
- abnormal dreams
- agitation
- having a swollen stomach (abdominal distention), wind (flatulence), indigestion (dyspepsia)
- having pain
- having neck pain
- difficulty swallowing or change in taste (bitter taste)
- uneven beats of the heart.

Impulse control disorders – changes in your behaviour. These are common, may affect up to 1 in 10 people.

Some people are unable to resist the impulse to do something that could be harmful to themselves or others. This may include

- a strong impulse to gamble too much, despite serious effects on you or your family
- a change or increase in sexual thoughts and behaviour of significant concern to you or to others. This could include an increased sexual drive.
- excessive shopping or spending too much, which cannot be controlled
- binge eating – eating large amounts of food in a short time, or compulsive eating – eating more food than normal and more than your body needs.

Tell your doctor if you, your family, or carer notice any of these behaviours. Your doctor may need to review your treatment. They will discuss ways of managing or reducing these symptoms with you.

Uncommon: may affect up to 1 in 100 people
- craving for large doses of Produodopa beyond what is required to control motor symptoms, known as dopamine dysregulation syndrome
- dark urine
- hoarse voice, chest pain
- hair loss, red skin, hives
- having more saliva than usual
- a change in the way you walk
- trying to end your own life or ending your own life, suicide
- low number of white blood cells or changes in blood cell counts which may cause bleeding
- elevated mood (euphoric mood), increased sexual interest, dementia, feeling of fear
- problems in controlling movements and making strong movements you cannot control
- problems opening your eyes, double vision, blurred vision, optic nerve damage (optic ischaemic neuropathy)
- irregular heartbeat that you can feel (palpitations).
- confusion
- nightmare
- swelling of a vein

Rare: may affect up to 1 in 1,000 people
- grinding of your teeth
- painful erection that will not go away
- unusual marks or moles on your skin that appear or get worse, or tumour of the skin (malignant melanoma)
- dark saliva or sweat, burning feeling on your tongue, hiccups.
- unusual thoughts
- unusual breathing

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Produodopa

Keep this medicine out of the sight and reach of children.

Keep the vials in the outer carton in order to protect the vials from breaking.

Do not use this medicine after the expiry date which is stated on the vial label and carton. The expiry date refers to the last day of that month.

- Do not freeze.
- Store and transport refrigerated (2°C to 8°C).
- Vials may be kept at room temperature up to 30°C for a single period of up to 28 days.
- The carton includes a space for recording the date when you remove the medicine from the refrigerator.
- Once the medicine has been stored at room temperature, do not return the medicine to the refrigerator.

- Discard the medicine if not used within the 28-day room temperature period.
- The entire contents of the vial should be transferred all at one time into a syringe for administration.
- Do not re-use an opened vial, they are for single use only.
- After opening: Use immediately. Use Produodopa within 24 hours once it has been transferred from the vial to the syringe.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- Discard the vial after transfer of the medicine to the syringe.
- Discard the syringe and any unused medicine in the syringe after the medicine has been in the syringe for 24 hours.

6. Contents of the pack and other information

What Produodopa contains

- The active ingredients are foslevodopa and foscarbidopa. 1 ml contains 240 mg foslevodopa and 12 mg foscarbidopa.
- 1 vial of 10 ml contains 2400 mg foslevodopa and 120 mg foscarbidopa.
- The other ingredients are sodium hydroxide 10N (for pH adjustment), hydrochloric acid, concentrated (for pH adjustment) and water for injections.

What Produodopa looks like and contents of the pack

Produodopa is a clear to slightly opalescent, particle free, solution provided in a clear, colourless glass vial closed with a grey rubber stopper and a turquoise plastic cap. The colour of the solution may vary from colourless to yellow to brown, and it 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.

Each pack contains 7 vials of 10 ml each.

Sterile, single-use infusion components (syringe, infusion set and vial adapter) qualified for use, are provided separately by your doctor or pharmacy. The Vyafuser pump is provided separately.

Marketing Authorisation Holder

AbbVie Ltd.
Maidenhead,
SL6 4UB
UK
Tel: +44 (0) 1628 561090

Manufacturer

AbbVie S.r.l.
04011 Campoverde di Aprilla
(Latina)
Italy

AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen
Germany

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To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the Marketing Authorisation Holder.

Other sources of information

Detailed information on this medicine is available on the website of Medicines and Healthcare products Regulatory Agency; www.mhra.gov.uk.

7. Instructions for use for Produodopa infusion using the Vyafuser pump

Please read all of the section below before using Produodopa

Important information

Read the instructions below carefully – these instructions explain how to prepare and use Produodopa.

- Produodopa is given by subcutaneous infusion with the aid of the Vyafuser pump and its infusion components (syringe, infusion set, and vial adapter).
- You can get your infusion set components from your doctor or pharmacy.
- You must also carefully read the full instructions prior to using Produodopa
    - vial adapter instructions for use
    - infusion set instructions for use
    - patient instructions for use of Vyafuser pump.
- Your doctor or nurse will set the pump up for you, so you always get the right dose.
- Your doctor or nurse will tell you how to take the medicine and how to handle the pump before you start treatment.
- If anything is unclear – please ask your doctor or nurse.

How to prepare your medicine

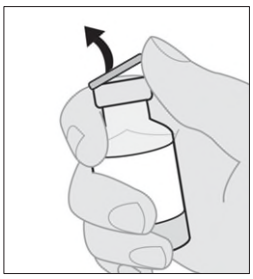
- Do not dilute the Produodopa solution or fill the syringe with any other solution.
- The medicine should be at room temperature prior to infusion. If refrigerated prior to use, remove the vial from the refrigerator and allow to sit at room temperature out of direct sunlight for 30 minutes. If refrigerated, do not warm the medicine (in the vial or syringe) in any way other than leaving it at room temperature. For example, do not warm in a microwave or in hot water.

1. Setting up

Follow the steps below every time you need to refill your pump with Produodopa.

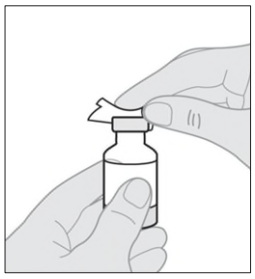
- Wash your hands with soap and water and dry them.
- Make sure your flat surface is clean. This will help to avoid contamination when you prepare the syringe.
- Place the following on the flat surface
    - Syringe (in its packaging)
    - Produodopa solution vial
    - Vial adapter (in its packaging). A new vial adapter must be used with each new Produodopa solution vial.
    - Alcohol pads (not provided with the medicine)
- Inspect the vial, vial adapter and syringe for expiry date and for any packaging damage
    - Do **not** use the vial, vial adapter or syringe if their sterile packaging has been damaged.
    - Do **not** use the Produodopa solution, vial adapter or syringe if it has passed the expiry date.
    - Do **not** use if the Produodopa solution is cloudy or contains flakes or particles.

2. Preparing the solution vial

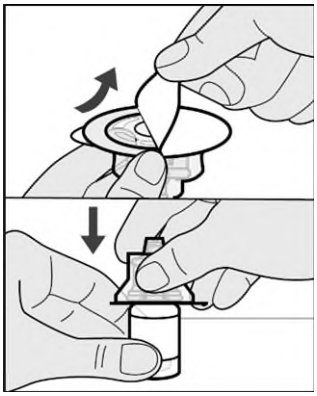


1) Prepare solution vial.

a. Remove the plastic cap from the solution vial.



b. Wipe the top of the solution vial with an alcohol pad and allow to dry.



2) Attach vial adapter to solution vial

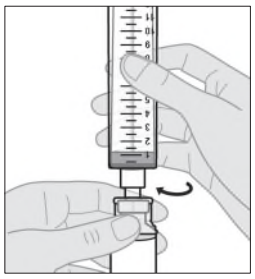
Your vial adapter may look different from the one shown in this section.

a. Peel off the paper cover from the vial adapter packaging. Keep the adapter in the plastic packaging for step 3.

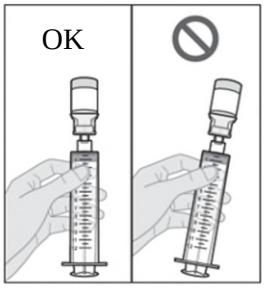
b. Use the packaging to push the vial adapter firmly, straight down onto the solution vial until it snaps into place.

c. Pull the packaging straight off the vial adapter.

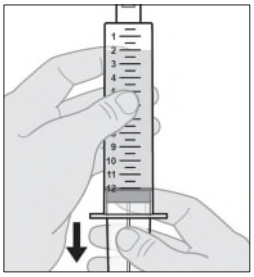
For detailed information see the *vial adapter instructions for use*.



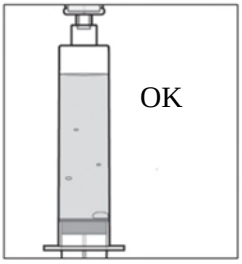
3) While holding the vial adapter firmly, attach the syringe to the vial adapter by pushing and then screwing it into place (clockwise). Do not overtighten.

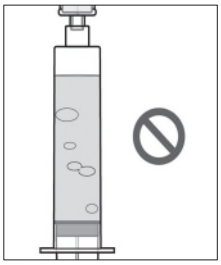


4) Turn it upside down and hold the syringe vertically with the solution vial on top.
5) It is important to hold the syringe pointing straight up.

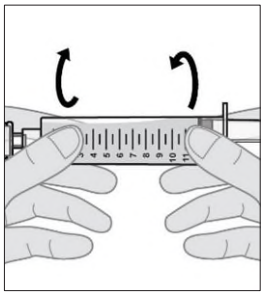


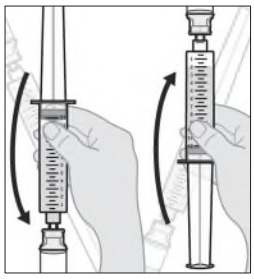
6) While holding the syringe firmly in one hand, pull down the plunger rod with the other hand to withdraw the full contents of the solution vial into the syringe to around the 12 ml mark or until you see air at the tip of the syringe.
   a. Make sure you withdraw the entire contents of the solution vial into the syringe.
   b. You will see air (head space) at the tip of the syringe.



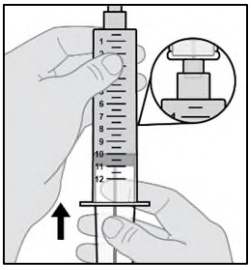


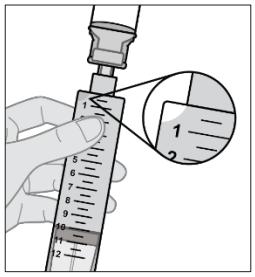
7) Inspect for air bubbles.
   a. Small bubbles are acceptable and the air at the tip of the syringe is expected If you see small air bubbles or do not see any bubbles, skip the next section and go to Step 9: Push air out of the syringe.
   b. If there are large air bubbles, they must be removed. If you see large air bubbles, continue to the next section, Step 8: Manually remove air bubbles.



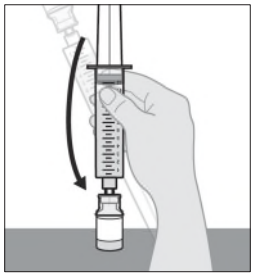


8) Manually remove air bubbles
   a. Slowly and gently rotate the syringe and tilt it back and forth. This will gather the bubbles into a single bubble. Do not shake or tap the syringe to remove the air bubbles.
   b. If there are still air bubbles, gather the bubbles by gently rotating the syringe end over end.
   c. When the large bubbles have gathered into one bubble continue with the next step.

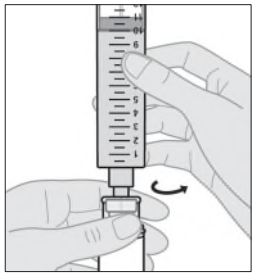




9) Push air out of the syringe.
   a. With the solution vial still attached, point the syringe upward.
   b. Slowly push the air out of the syringe and into the vial. Some resistance will be felt as the air is pushed back into the solution vial.
   c. Continue pushing until all of the air is pushed out of the syringe and into the solution vial and there is solution visible in the syringe tip.
   d. If you are tilting the syringe, you may see a small air bubble in the corner. This is acceptable.



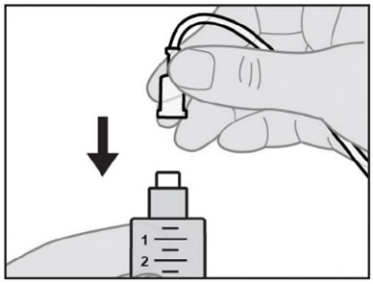
10) Turn over the syringe and solution vial so that the solution vial is upright on the flat surface.



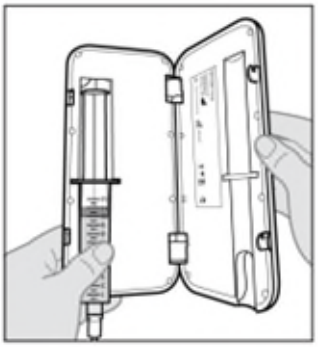
11) Disconnect the syringe from the vial adapter.
   a. Hold the vial adapter firmly with one hand and the barrel of the syringe with the other.
   b. Unscrew the syringe from the vial adapter. When disconnecting the syringe from the vial, do not push the plunger or the solution will leak.
   c. Place the syringe on a clean surface, making sure the syringe tip does not contact an unclean surface.

12) Your syringe is now ready for use.

3. Setting up your Produodopa infusion



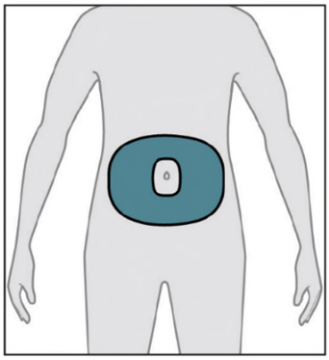
- Attach the infusion set tubing to the new syringe.
  - While holding the syringe firmly, attach the infusion set tubing to the syringe and twist until tight.
  - See the *infusion set instructions for use* for detailed instructions.



- Place the syringe into the pump.
  - See *patient instructions for use of Vyafuser pump* for detailed instructions.

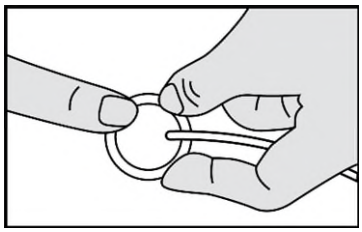
- Prime the infusion set tubing. Priming means that the pump pushes your medicine from the syringe through the infusion set tubing to eliminate air in the line.
  - See *patient instructions for use of Vyafuser pump* for detailed instructions.

4. Choosing and preparing the infusion site



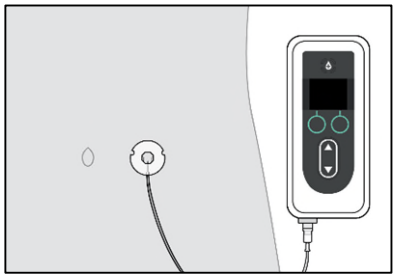
- Choose an area shown (in the abdomen) at least 5 cm from the navel.
- Avoid any skin that is scarred, hardened tissue, stretch marks, or skin folds or creases where the body naturally bends a great deal, or to areas where clothing might cause irritation (e.g., near the beltline).
- Open an alcohol pad and wipe the chosen infusion site with an alcohol pad and let it air dry for at least 1 minute.

See *infusion set instructions for use* and *patient instructions for use of Vyafuser pump* for detailed instructions.



- Attach cannula to body and the infusion set to cannula.
  - Insert the cannula into your body.
  - Connect the infusion tubing to the cannula.
  - See *infusion set instructions for use* for detailed instructions.

5. Start Produodopa infusion



- Start pump. See the *patient instructions for use of Vyafuser pump* for detailed information.

- Pump delivery options

	Purpose	When it is available
Continuous Infusion	Main mode that delivers a continuous dose of Produodopa throughout the day.	Always available, as prescribed.
Extra Dose	A small, single-volume dose given over a short period of time (bolus) to achieve the desired level of medicine in your body quickly. The Extra Dose is only available if it is set up by your doctor.	Available as needed, defined by a pre-set Extra Dose lockout time.
Loading Dose	A large single dose given over a short period of time (bolus) that may be delivered to achieve the desired level of medicine in your body quickly, only available after the Pump has been off for an extended period and if it is set up by your doctor.	After the medicine has not been delivered for an extended period of time, defined by the Loading Dose lockout time (minimum of 3 hours).

- The pump has alternative delivery options available which can be set up by your doctor if needed.

6. After Use

- Used solution vials with the vial adapter still attached should be disposed of in accordance with local regulations or as directed by your doctor, pharmacist, or nurse.