PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

PRODUODOPA™

Solution for subcutaneous infusion

The active ingredient and its quantity:
Each vial contains:
Foslevodopa 240 mg/ml
Foscarbidopa 12 mg/ml

For the list of inactive ingredients, please see section 6 'Further information' and section 2 'Important information about some of the medicine's ingredients' in this leaflet.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your ailment/you. Do not pass it on to others. It may harm them even if you think that their ailment/medical condition is similar.

In addition to the leaflet, there is a Patient Safety Card for Produodopa. This card contains important safety information you must know and adhere to before starting and during the course of treatment with Produodopa. Read the Patient Safety Information Card and the patient leaflet before starting to use the preparation. Keep the card for further reading, if needed.

1. WHAT IS THE MEDICINE INTENDED FOR?

What Produodopa is used for
Produodopa is intended for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia, when available combinations of Parkinson medicinal products have not given satisfactory results.

Therapeutic group: Anti-Parkinson's medicines, foslevodopa and decarboxylase inhibitor.

How Produodopa works
- In the body, foslevodopa turns into dopamine, which is added to the dopamine already in your brain and spinal cord. Dopamine helps transfer signals between nerve cells.
- Too little dopamine causes Parkinson's disease symptoms, such as: 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. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients, or to any of the additional ingredients contained in the medicine (for the list of inactive ingredients, see section 6).
- you have an eye problem called 'narrow-angle glaucoma'.
- you have severe heart problems.
- you have severe heart rhythm disturbances (arrhythmia).
- you have an acute stroke.
- you 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 starting treatment with Produodopa.
- you have a tumor of the adrenal gland (pheochromocytoma).
- you have hormone problems such as too much cortisol (Cushing's syndrome), or your thyroid hormone levels are too high (hyperthyroidism).
- you have ever had skin cancer, or you have any unusual moles or marks on the skin which have not been looked at by your doctor.

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

Special warnings regarding the use of the medicine
Before treatment with Produodopa, tell the doctor if:
- you have ever had a heart attack, blocked blood vessels in your heart, or any other heart problems, including heart rhythm disturbances (arrhythmia).
- you have a lung problem, such as asthma.
- you have ever had a hormone problem.
- you have ever had depression with suicidal thoughts or other mental problems.
- you have an eye problem called 'wide-angle glaucoma'.
- you have ever had a stomach ulcer.
- you have ever had fits (convulsions).
- you have a kidney or liver disease.
- you are on a controlled sodium diet (see 'Important information about some of the medicine's ingredients').
- you have skin changes at the infusion site such as redness, warmth, swelling, pain, or discoloration when applying pressure to the area.
- you have progressive weakness, pain, numbness or loss of sensation in the fingers or legs (polyneuropathy). Your doctor will check for these signs and symptoms before treatment with Produodopa is initiated 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 conditions apply to you or if you are not sure, consult your doctor before using the medicine.

Tell the doctor if you notice involuntary and uncontrollable movements of the limbs, back, neck, or chin (dyskinesia) or an increase in stiffness or slowness of movements. Your daily dosage 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 behavior
Tell your doctor if you, your family, or caregiver notices you are developing urges or cravings to behave in ways that are unusual for you, or that you cannot resist the impulse, drive, or temptation to carry out certain activities that could harm yourself or others. These behaviors are called 'impulse control disorders' and can include:
- addictive gambling
- excessive eating or money spending
- abnormally high sex drive or an increase in sexual thoughts or feelings

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

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

Infusion site infections
Tell the doctor if you notice any skin changes at the infusion site, such as redness, warmth, swelling, pain, or discoloration when applying pressure to the area. You should always follow aseptic (sterile) techniques while using this medicine and regularly change the infusion site (at least every 72 hours), 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 72 hours, if you notice any of the above-mentioned skin changes.

Produodopa and cancer
In the body, foscarbidopa (one of the active ingredients of Produodopa) is broken down into a substance 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 dosage of Produodopa can cause this.

Children and adolescents
Produodopa is not intended for children and adolescents under 18 years of age. There is no information regarding the safety and efficacy of use of Produodopa in children and adolescents under 18 years of age.

Interactions/Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:
- medicines to treat tuberculosis – such as isoniazid
- medicines to treat anxiety – such as benzodiazepines
- medicines to treat nausea or vomiting – such as metoclopramide
- medicines to treat high blood pressure
- medicines to treat spasms in the blood vessels – such as papaverine
- medicines to treat fits (convulsions) or epilepsy – such as phenytoin
- medicines to treat psychiatric disease – such as anti-psychotics including phenothiazines, butyrophenones and risperidone
- medicines to treat Parkinson's disease – such as tolcapone, entacapone, opicapone and amantadine
- medicines to treat depression – such as tricyclic antidepressants including amoxapine and trimipramine

Tell the doctor or pharmacist if you are taking medicines from the COMT (catechol-O-methyl-transferase) enzyme inhibitor group, which may increase levodopa levels in your blood. Your doctor may need to adjust the dosage of either medicine.

Tell your doctor or pharmacist if you are taking medicines called sympathomimetic drugs such as - but not limited to - salbutamol (to treat asthma), phenylephrine (anticongestant), isoproterenol, dobutamine to treat low blood pressure. Use of Sympathomimetic medicines together with 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 to improve mood)
- clozapine (to control schizophrenia)
- theophylline (helps with asthma)

Certain medicines (such as selegiline) that you take may lower your blood pressure, and may therefore make you feel dizzy when you get up from a chair or bed (orthostatic hypotension). Produodopa may 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 to treat depression called selective MAO-A inhibitors and non-selective MAO inhibitors such as moclobemide or phenelzine.

Use of the medicine and food
Since Produodopa is not administered to the digestive system, food has no effect on the medicine.

Pregnancy, breastfeeding and fertility
Pregnancy
There is no information regarding use of Produodopa in pregnant women.
If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, consult your doctor 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 risks to the unborn baby.

Breastfeeding
It is not known if Produodopa passes into breast milk. Stop breastfeeding during treatment with Produodopa.

Driving and using machinery
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 suddenly fall asleep (sleep attacks).
- Produodopa may lower your blood pressure, and make you feel dizzy.

Do not drive or use any tools or machinery until you feel fully awake again or you no longer feel dizzy.

Important information about some of the medicine's ingredients
Produodopa contains a high amount of sodium. Talk to the doctor or pharmacist if you need 9 ml or more of Produodopa per day for a prolonged period, especially if you have to follow a low-sodium diet.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and the treatment regimen of the medicine.

How to use Produodopa
- Before starting treatment, you or your caregiver will be trained in how to use the medicine and the infusion pump.
- Produodopa is a solution that is administered under your skin (a form called subcutaneous infusion) most frequently in the abdomen, using an infusion pump. You should avoid using the infusion pump in the 5 cm radius circular area around the navel.
- The nurse will adjust the pump settings, so the dosage fits your 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.

Dosage
The dosage and treatment regimen will be determined by the doctor only.
- Your doctor will decide how much Produodopa you should use and for how long. Usually, a continuous maintenance dose will be given to you.
- If needed, you may have extra doses (an available option on your pump) will be given to you to manage sudden "Off" symptoms which may occur 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) before resuming the continuous infusion to quickly re-establish your symptom control.

Read section 7 'Instructions for Use of Produodopa infusion using the Vyafuser™ pump' before using Produodopa.

Do not exceed the recommended dose.

If you accidentally take a higher dosage of Produodopa
If you have used more Produodopa than you should, stop the infusion immediately and talk to your doctor or go to a hospital emergency room straight away and bring the medicine's package with you. The following effects may happen:
- unusual fast, slow or uneven heartbeats (arrhythmia)
- low blood pressure (hypotension)

If you forget to take Produodopa or stop using Produodopa
If you forgot to use Produodopa, start the pump with your normal dosage as soon as possible.
Produodopa can be interrupted for brief periods of time, such as when taking a shower. Make sure to change the infusion set (tubing and cannula) and rotate to a different infusion site if you stopped the infusion for longer than one hour. For interruptions longer than 3 hours, you may need to self-administer a loading dose to quickly re-establish your symptom control. The loading dose option is available in your pump, as set by the doctor or nurse.

Do not stop the treatment or lower the dosage of Produodopa unless the doctor has instructed you to do so. Suddenly stopping or lowering Produodopa dose quickly may cause a serious problem called "Neuroleptic Malignant Syndrome" (see section 2 'Neuroleptic Malignant Syndrome').

Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of Produodopa may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using Produodopa and refer to a doctor immediately if you notice any of the following serious side effects. You might need urgent medical treatment:
- angle-closure glaucoma (acute eye pain, 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 and cannot be estimated from available data.

Your doctor will decide if you can continue using Produodopa.

Very common side effects – effects that occur in more than one user in ten:
- infusion site infection (infusion site cellulitis) (see section 2 'Infusion site infections')
- anxiety
- seeing, hearing or feeling things that are not there (hallucinations)
- depression
- infusion site reactions (redness, appearance of a mass, swelling, pain)
- falling
- urinary tract infections.

Common side effects – effects that occur in 1-10 in 100 users:
- infusion site effects (bruising, peeling of thin layers of skin, leakage of the medicine, bleeding, inflammation, irritation, appearance of a mass, appearance of a bump, itching, rash)
- infusion site abscess
- decreased appetite
- confusion
- false beliefs (delusions)
- paranoia
- thoughts to end your own life (suicidal thoughts)
- problems with the ability to think, learn and remember (cognitive disorder)
- involuntary movements (dyskinesia)
- uncontrollable muscle spasms – that affect the eyes, head, neck and body (dystonia)
- headache
- reduced sense of touch, tingling or numbness, burning or prickling feeling in the hands, arms, legs or feet (hypoesthesia, paresthesia)
- progressive weakness or pain or numbness or loss of sensation in the fingers or feet (polyneuropathy)
- rapid or unexpected return of Parkinson's symptoms – 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 standing up or changing positions (orthostatic hypotension, postural dizziness) – due to low blood pressure. Always change positions slowly and do not stand up quickly
- fainting
- abdominal pain
- constipation
- dry mouth
- nausea, diarrhea, or vomiting
- unable to control urine (urinary incontinence)
- difficulty passing urine (urinary retention)
- lack of energy, feeling weak (fatigue)
- swelling in the lower legs or hands caused by too much fluid (peripheral edema)
- 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
- anemia
- abnormal dreams
- agitation
- having a feeling of a swollen stomach (abdominal distention), flatulence, indigestion (dyspepsia)
- pain sensation
- having neck pain
- difficulty swallowing or changes in taste (bitter taste)
- uneven heartbeats.

Impulse control disorders – changes in your behaviour. These effects 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 implications for 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 the doctor if you, your family, or caregiver notices any of these behaviours. The doctor may review your treatment. The doctor will discuss ways of managing or reducing these symptoms with you.

Uncommon side effects – effects that occur in 1-10 in 1,000 users:
- craving for high dosages of Produodopa beyond what is required to control motor symptoms, known as 'dopamine dysregulation syndrome'
- dark urine
- hoarse voice, chest pain
- hair loss, skin redness, hives
- having more saliva than usual
- a change in the way you walk
- suicide attempts or suicide
- low number of white blood cells or changes in blood cell count which may cause bleeding
- elevated mood (euphoria), increased sexual interest, dementia, feeling of fear
- problems in controlling movements and making strong movements you cannot control
- problems opening the eyes, double vision, blurred vision, optic nerve damage (optic ischemic neuropathy)
- irregular heartbeat that you can feel (palpitations).
- confusion
- nightmare
- swelling of veins

Rare side effects – effects that occur in 1-10 in 10,000 users:
- teeth grinding
- painful erection that does not pass
- unusual marks or moles on the skin that appear or get worse, or skin tumor (malignant melanoma)
- dark saliva or sweat, burning feeling on your tongue, hiccups.
- unusual thoughts
- unusual breathing

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), which directs you to the online form for reporting side effects or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store refrigerated (between 2°C-8°C). Do not freeze.
- The vials can be stored at room temperature up to 30°C for a single period of up to 28 days.
- The carton package includes a space designated for recording the date of removal from the refrigerator.
- Once the medicine has been stored at room temperature, do not return it to the refrigerator.
- Discard the medicine if not used within 28 days when stored at room temperature.
- The entire contents of the vial should be transferred all at once into the syringe for administration. Then, throw away the empty vial.
- Do not reuse an opened vial. The vial is for single use only.
- After opening the vial, use immediately. Use Produodopa within 24 hours once it has been transferred from the vial to the syringe. Do not use the syringe and any unused medicine in the syringe after 24 hours.
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:
water for injection, sodium hydroxide 10N, hydrochloric acid, concentrated/hydrochloric acid, nitrogen.

What the medicine looks like and the contents of the package:
Colorless to yellow to brown solution that might have a purple or red tint. Variations in color are expected and have no impact on medicine quality. The solution may become darker in color after piercing of the vial stopper or while in the syringe.
Each pack contains 7 vials of 10 ml each.
Sterile, single-use accessories (syringe, infusion set and vial adapter) will be provided separately.
The Vyafuser™ pump is provided separately.

- Registration holder and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.
- Manufacturer and address: AbbVie Inc. 1 North Waukegan Road, North Chicago, Illinois 60064, USA.
- Revised in December 2023 according to MoH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 173-60-37468-99

7. INSTRUCTIONS FOR USE OF PRODUODOPA INFUSION USING THE VYAFUSER™ PUMP

Read all the entire section below before using Produodopa.

Important information
Carefully read the instructions below – these instructions explain how to prepare and use Produodopa.
- Produodopa is given by subcutaneous infusion with the aid of the Vyafuser pump and its components (syringe, infusion set, vial adapter).
- You must also carefully read the full instructions for use before using Produodopa:
  - vial adapter instructions for use
  - infusion set instructions for use
  - Vyafuser pump instructions for use
- The nurse will adjust the pump settings for you, so you will always get the right dose.
- Before you start treatment, your doctor or nurse will tell you how to take the medicine and how to handle the pump.
- If anything is unclear and if you have any question, refer to your doctor or nurse.

How to prepare the medicine
- Do not dilute the Produodopa solution or fill the syringe with any other solution.
- The medicine must be at room temperature before the infusion. If the vial was refrigerated prior the infusion, remove the vial from the refrigerator and allow to sit at room temperature out of sunlight for 30 minutes. If the medicine is refrigerated, do not warm it (whether it is 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.

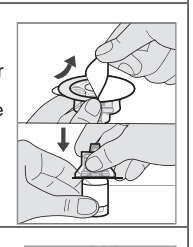
1. Setting up
Follow the steps below every time you need to refill your pump with Produodopa.
- Wash your hands with soap and water and dry them.
- Make sure the flat surface is clean. This will help to avoid contamination when preparing the syringe.
- Place the following items on the flat surface:
  - Syringe (in its original package)
  - Produodopa solution vial
  - Vial adapter (in its original package). Use a new vial adapter with each new Produodopa solution vial.
  - Alcohol pads
- Inspect the vial, vial adapter and syringe for expiry date and for any defects.
  - **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 the expiry date has passed.
  - **Do not** use the Produodopa solution if it is cloudy or contains flakes or particles.

2. Preparing the solution syringe

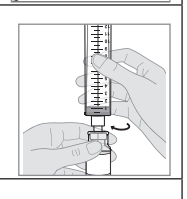
1) Prepare solution vial.
A. Remove the plastic cap from the solution vial.

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

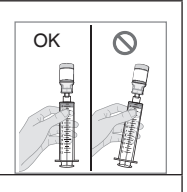
2) Attach vial adapter to solution vial.
The vial adapter may look different from the one shown in the picture.
A. Peel off the paper cover from the vial adapter package. Keep the vial adapter in the plastic packaging for step 3.
B. Use the packaging to push the vial adapter firmly, straight down onto the solution vial until it snaps into place.
C. Pull the packaging straight off of the vial adapter.
For detailed information, see the *vial adapter instructions for use*.



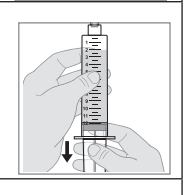
3) While firmly holding the vial adapter, attach the syringe to the vial adapter by pushing and then screwing it into place (clockwise). Do not overtighten.



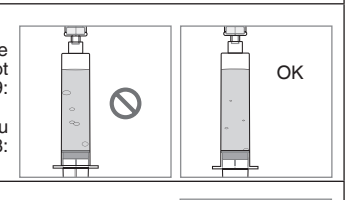
4) Turn it upside down and hold the syringe vertically, with the solution vial on top.
5) It is important to hold the syringe pointing straight up.



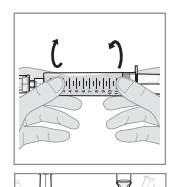
6) While holding the syringe firmly in one hand, pull down the plunger rod with the other hand to withdraw the full contents of the solution vial into the syringe to the 12 ml mark or until you see air at the tip of the syringe.
A. Make sure you withdraw the entire contents of the solution vial into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

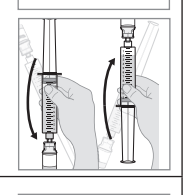


7) Inspect for air bubbles.
A. Small bubbles are acceptable and air at the tip of the syringe is expected. If you see small air bubbles or do not see any bubbles, skip the next section and go to Step 9: Push air out of the syringe.
B. If there are large air bubbles, they must be removed. If you see large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

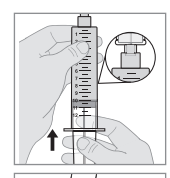


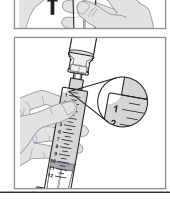
8) Manually remove air bubbles.
A. Slowly and gently rotate the syringe and tilt it back and forth. This will gather the bubbles into a single bubble. Do not shake or tap the syringe to remove the air bubbles.
B. If there are still air bubbles, collect the bubbles by gently rotating the syringe end over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



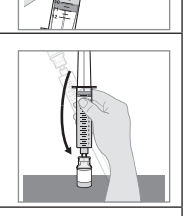


9) Push air out of the syringe.
A. With the solution vial still attached, point the syringe upward.
B. Slowly push the air out of the syringe and into the vial. Some resistance will be felt as the air is pushed back into the vial.
C. Continue pushing until all of the air is pushed out of the syringe and into the solution vial and solution is 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.

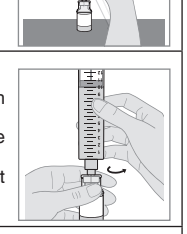




10) Turn over the syringe and solution vial so that the solution vial is upright on the flat surface.



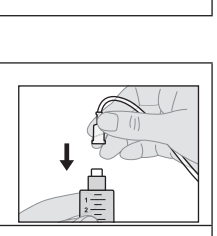
11) Disconnect the syringe from the vial adapter.
A. Hold the vial adapter firmly with one hand and the barrel of the syringe with the other.
B. Unscrew the syringe from the vial adapter. When disconnecting the syringe from the vial, do not push the plunger or the solution will leak.
C. Place the syringe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



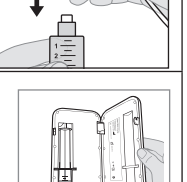
12) The syringe is now ready for use.

3. Setting up your Produodopa infusion

- Attach the infusion set tubing to the new syringe.
  - While firmly holding the syringe, 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 *Vyafuser pump instructions for use* for detailed instructions.

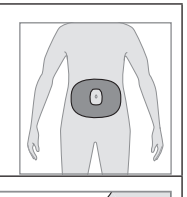


- Prime the infusion set tubing. Priming means that the pump pushes the medicine from the syringe through the infusion set tubing to eliminate air in the line.
  - See *Vyafuser pump instructions for use* for detailed instructions.

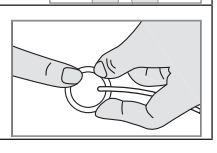
4. Choosing and preparing the infusion sites

- 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 areas where clothing might cause irritation (e.g., near the beltline).
- Wipe the chosen infusion site with an alcohol pad and allow it to air dry for at least 1 minute.

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

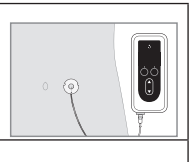


- Attach cannula to body and the infusion set to cannula.
  - Insert the cannula into your body.
  - Connect the infusion tubing to the cannula.
    See *infusion set instructions for use* for detailed instructions.



5. Start Produodopa infusion

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



- **Pump delivery options**

	Purpose	When option 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, the option is defined by the "Loading Dose" lockout time (minimum of 3 hours).

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

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