Patient Guide Produodopa®

(foslevodopa/foscarbidopa)

for advanced Parkinson's disease

This patient guide contains important safety information you should be aware of.

Please keep this guide available when you are preparing to use this medicine.



Why should I read this patient guide?

Produodopa[®] is a medicine to treat the symptoms of advanced Parkinson's disease.

It is used when other medicines no longer work as well as they did to treat the symptoms of the disease.

You or your caregiver will deliver this medicine under your skin through a small plastic tube (cannula) in the area around the belly button. This area is your infusion site.

It is delivered through this tube continuously 24 hours a day.

Some people using this medicine may have problems around the skin where the cannula goes into their body.

These could be:

- a skin infection. This is when germs get into the skin. A skin infection can become serious when germs enter the blood and spread all over the body. This is called sepsis.
- a skin reaction. This is when the skin becomes irritated / inflamed.

This patient guide will help you and your caregiver learn about:



How to choose your infusion site



How to recognise an infusion site infection or infusion site reaction



What you can do to help reduce the chance of an infusion site infection or infusion site reaction



What you should do if you have an infusion site infection or infusion site reaction



Where you can find more information about your medicine

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How to choose your infusion site

Changing your infusion site regularly is important. This is because it helps your skin stay healthy and lets the medicine be delivered correctly.

You can use your stomach for the infusion site unless your doctor tells you to use another site. Make sure where you choose is at least 5 cm away (about the length of your little finger) from your belly button.

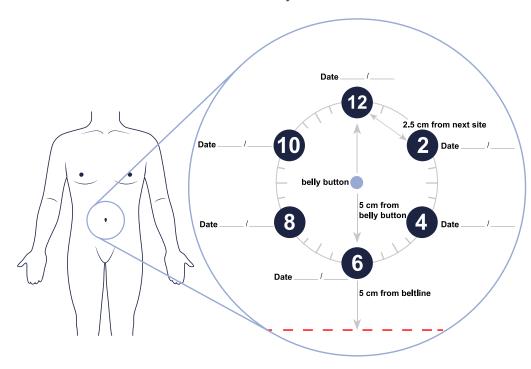
- Avoid your belt line because this area may be irritated by the pressure of the belt against the skin
- Avoid any skin that is scarred, hard, or has stretch marks
- Avoid any skin folds or creases on your skin where it naturally bends a lot
- Use a new infusion set (cannula/tubing), every time you change your infusion site.

Change your infusion site every 3 days or sooner depending on the changes to your skin (such as redness, swelling, and pain).

Your new infusion site must be at least 2.5cm (about the space of two fingers) away from the last one you used.

Once you have used an infusion site, do not use it again for 12 days. This will help your skin to heal completely.

There are different ways to help you remember not to reuse an infusion site too soon. One way is to pretend your stomach is a clock. You can put in your cannula at a different two 'hour' interval each time. You can start with the site at 12 o'clock, then 2 o'clock followed by 4 o'clock and so on.



Make a note of the date and place of your infusion sites to help you keep track.

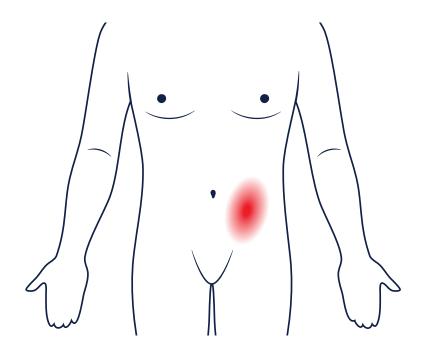
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How to recognise an infusion site infection or infusion site reaction

Look for skin changes where the cannula goes into your skin. The skin changes may happen with or without a fever and include:

- redness
- warm to touch
- swelling
- tenderness/pain
- changes in skin colour when you press on your skin





What you can do to help reduce the chance of an infusion site infection or infusion site reaction

Infusion site infections or infusion site reactions may happen. Below are elements to consider when handling the infusion.



Use a well-lit area that is clean and flat (such as a table) to prepare your infusion.



Keep the infusion site and the infusion set clean and sterile when you prepare the infusion.



Always wash your hands with soap and water and dry them with a paper towel. Do not touch anything unclean afterwards.



Avoid letting the tip of the syringe, vial adaptor, tubing, or site connector touch an unclean surface.



Carefully dispose of any of the used materials that may be contaminated.



When you have chosen an infusion site, wipe your skin with an alcohol pad or wipe. Make sure you wipe in one direction so that you do not contaminate the cleaned area. Allow the area to dry for at least 1 minute.

Change the infusion site every 3 days or sooner depending on the changes to your skin (such as redness, swelling, and pain)



When you use a new infusion site. do not choose the same infusion site for 12 days. This will help your skin to heal completely.



Always keep a 2.5 cm (about the space of two fingers) distance from the last infusion site you used.



Always use a new cannula and tubing when changing to a new infusion site.



Trim any hair around your infusion site with scissors. This will help the cannula tape stick to your skin. If you must shave your skin, wait one day before using that infusion site.



Wear comfortable clothes that will not irritate the skin at the infusion site.

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What you should do if you have an infusion site infection or infusion site reaction

Change your infusion site – do not wait for 3 days.

Call your doctor, nurse or pharmacist if you have the following symptoms:

- redness
- warm to touch
- swelling
- tenderness/pain
- changes in skin colour when you press on your skin

Do not reuse an infected site for at least 12 days or until it has healed.



Where you can find more information about your medicine

- For more information about your medicine, consult your product information leaflet (PIL) and the instructions for use (IFUs) that came with your medicine (foslevodopa/foscarbidopa).
- If you get any side effects, talk to your doctor, pharmacist or nurse.
 This includes any possible side effects not listed in this leaflet. You can also report side effects directly to HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.