

Important Risk Minimisation Information for Patients

Produodopa[®]

(foslevodopa/foscarbidopa)

for advanced Parkinson's disease

Patient Guide

This patient guide is essential to ensure the safe and effective use of the product and provides guidance on preventing and managing the risk of infusion site side effects (infection and reaction).

Please read this guide carefully, do not discard, and keep it available each time you are preparing to use this medicine.

abbvie

This page is left intentionally blank

Introduction to Produodopa

Produodopa® is a medicine to treat levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson's medicinal products have not given satisfactory results.

Produodopa contains foslevodopa 240 mg/ml and foscabidopa 12 mg/ml in a solution that is given as a continuous subcutaneous (under the skin) infusion and the body breaks down these medicines into levodopa and carbidopa.

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

The medicine will be infused under your skin through a small plastic tube (cannula) in the area around the belly button.

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

For more information about your medicine, consult your product information leaflet (PIL), and the instructions for use (IFUs) that came with your medicine (foslevodopa/ foscabidopa).

This guide tells patients and their carers about infusion site side effects and provides advice on how to prevent and manage them.

The main risks of Produodopa treatment are infusion site skin infections and infusion site skin reactions, these side effects are very common, affecting more than 1 in 10 people:

- **a skin infection.** This is when bacteria get into the skin

A skin infection can become serious when bacteria enter the blood and spread all over the body. This is called sepsis

- **a skin reaction.** This is when the skin becomes irritated / inflamed

Some infusion site infections require early treatment with antibiotics and interventions such as draining the abscess which your treating physician will decide. Please consult with your treating physician if you notice any signs of infection.

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

- How to choose and prepare your infusion site
- What you can do to help reduce the chance of an infusion site infection or infusion site reaction
- How to recognise an infusion site infection or infusion site reaction
- What you should do if you have an infusion site infection or infusion site reaction
- How to report side effects

How to choose and prepare 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 abdomen for the infusion site unless your doctor tells you to use another site. Make sure where you choose is at least 5 cm / 2 inches away (about the length of your little finger) from your belly button.

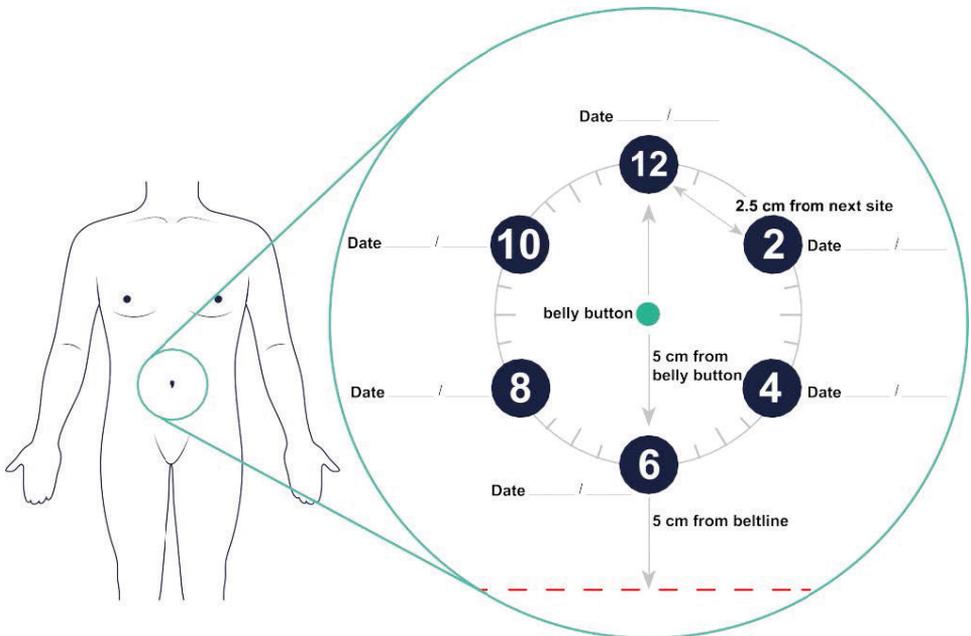
- **Avoid your belt line because this area may be irritated by the pressure of the belt against the skin**
- **Avoid any skin that is scarred, hard, or has stretch marks**
- **Avoid any skin that is tender, bruised or red**
- **Avoid any skin folds or creases on your skin where it naturally bends a lot**
- **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 2.5 cm / 1 inch (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 abdomen 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.

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.

- Always wash your hands with soap and water and dry them with a paper towel. Do not touch anything unclean afterwards.
- Use a well-lit area that is clean and flat (such as a table) to prepare your infusion.
- 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.
- Keep the infusion site and the infusion set clean and sterile when you prepare the infusion.
- 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.

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

- You should set up and prepare your Produodopa infusion as instructed by your healthcare professional using aseptic techniques and avoid contaminating clean areas.
- 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.
- Wear comfortable clothes that will not irritate the skin at the 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.
- Always use a new cannula and tubing when changing to a new infusion site.
- Always keep a 2.5 cm / 1 inch (about the space of two fingers) distance from the last infusion site you used.

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

An untreated skin infection can sometimes spread and cause sepsis. The possible symptoms of sepsis include:

- Feeling very unwell
- Not passing urine all day
- Continual vomiting and being unable to keep any food down
- A rash that does not fade when you roll a glass over it (if applicable)
- A very high or low temperature, feeling hot or cold to the touch, or shivering
- Acting confused, slurred speech or not making sense
- Blue, grey, pale or blotchy skin, lips or tongue – on brown or black skin, this may be easier to see on the palms of the hands or soles of the feet
- Difficulty breathing, breathlessness or breathing very fast

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

Change your infusion site immediately – do not wait for 3 days. If your skin shows any signs of a reaction or infection then call your doctor, nurse or pharmacist for advice. If you have a rash that's red, swollen, tender and warm and the affected area is getting bigger then contact your doctor as soon as possible.

Seek immediate medical attention if you develop any symptoms of sepsis.

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

How to report side effects

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this booklet or the Patient Information Leaflet.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

If you have any questions or queries, please do not hesitate to contact the Produodopa Helpline: 08081 756665