



Clinical Visit Recommendations

In addition to important aspects outlined within the Home Visit section of this document we recommend the following be addressed during the clinical visit. Patients should fill in an on/off schedule during at least a two day period, prior to the clinical visit. Five days in a month is sufficient or as instructed by the physician.

Effect of Doses (as described in home visit section)

Evaluate the on/off schedule together with the patient and discuss:

- How is the effect of the morning dose?
- How are your on-time and off-time periods? (related to the continuous dose)
- Do you find that you need any extra dose(s) during the day? (If yes, ask the patient to provide details on number of extra doses needed per day. If the patient responds that they are taking more than 5 additional doses per day, advise patient to contact their prescribing physician)
- How is the effect of the extra dose(s)?

Social situation & mood

- Tell me about your social activities. (Have your social activities increased?)
- Do you experience an improvement related to activities? Are there any activities that you can do now but couldn't do before?
- Have you noticed a change in your mood? If yes, has your mood improved or worsened? (If the answer is worsened, advise patient to contact their prescribing physician)
- Do you feel that you are motivated and have energy? Has it changed over time?
- Have you noticed any urges or cravings to behave in ways that are unusual for you, like addictive gambling, excessive eating or spending, abnormally high sex drive or an increase in sexual thoughts or feelings? (If yes advise patient to contact their prescribing physician)

Nights

- How are the nights?
- Are you taking any anti-Parkinson tablets in the evening or during the night?
- Do you have any nightmares/vivid dreams?
- Do you have problems with insomnia?

Dose Management

Here you should find out if the patient is handling the doses correctly

- Have you changed any of the doses; morning, continuous and extra dose?
- If so, which of those doses and how often do you change them?
- Do you need any extra dose(s) during the day? If so how many extra doses do you need per day?

Do you take rescue medication, except L-dopa formulation, at home?

- Apomorphine sc?
- Other?

Stoma

Ensure that there are no complications or early signs of complication

- How does the stoma look?
- Is it clean?
- Is it dry?
- Are there any signs of swelling, redness or irritation?
- Do you have pain in the stomach?

Tube related questions:

- Do you manage to flush the intestinal tube in the evenings?
- Are the connectors on the PEG-J tube looking proper? (Check)
- Are the connections and tube clean and dry? (Leakage?)
- The gastric port (the Y-part) of the tube should be flushed once a day, do you have any problems with this?

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie. E-mail: medsafety@hpra.ie

Important Risk Minimisation Information

Best Practice Patient Aftercare





Patient At-Home Call/Visit Recommendations

Overview

This patient aftercare guide informs Healthcare Professionals about aftercare recommendations to minimise potential complications of PEG-J placement in patients using Duodopa. Please carefully read this guide and adopt these best practices into your patient care.

Duodopa is indicated for the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.

Duodopa is a gel for continuous intestinal administration. For administration of Duodopa only the CADD-Legacy 1400 pump (CE 0473) should be used. A manual with instructions for using the portable pump is delivered together with the pump.

Recommended Follow-Up Schedule For Patients Using Duodopa System

Each patient has different needs, the follow-up schedule and questions might therefore need to be adopted for each individual patient. Use the recommended follow-up schedule below for aftercare consultation for your patients with PEG-J insertion while on Duodopa treatment.

Period After Patient Discharge	Call/Visit the Patient at Home	Clinical Visit
Day 1	✓	
Day 3	✓	
Day 12	✓	
One month		✓
Six weeks	✓	✓
Two months	✓	
Three months		✓
Five months	✓	
Six months		✓

Important aspects to be addressed during each telephone call or visit at the patient's home

Effect of Doses How are your days?

- How is the effect of the morning dose?
- How are your on-time and off-time periods? (related to the continuous dose)
- Do you find that you need any extra dose(s) during the day (If yes, ask the patient to provide details on number of extra doses needed per day. If the patient responds that they are taking more than 5 additional doses per day, advise patient to contact their prescribing physician)? How is the effect of the extra dose(s)?
- How are the nights? Are you taking any anti-Parkinson tablets in the evening or during the night?

Practical Pump and Tube Handling Have you had any issues with the pump or tube?

Pump related questions:

- Are you able to start, stop and take extra doses (if needed) with the pump?
- Are you able to connect the system, the pump to the cassette and the cassette to the PEG-J tubes?
- Have you had any alarms? (If yes, ask the patient if he/she was able to identify the cause of the alarm(s) and resolve the issues. Please refer to the patient pocket guide for the common alarms that you may hear from the pump and actions to take.)
- Have you changed the battery in the pump? If so, were you able to do that without problems?



Tube related questions:

- Do you manage to flush the intestinal tube in the evenings?
- Are the connectors on the PEG-J tube looking good (i.e., no leakage or loosening of the tube or connectors)?
- Are the connections and tube clean and dry? (Leakage?)
- The gastric port, (the "Y-Part"), of the tube should be flushed once a day. Do you have any problems with this?

Stoma Ensure that there are no complications or early signs of complication

- How does the stoma look?
- Is it clean?
- Is it dry?
- Are there any signs of swelling, redness or irritation?
- Do you have pain in the stomach?



IMPORTANT AFTERCARE INSTRUCTIONS

- ✓ Flush the AbbVie™ J-tube and PEG daily with room temperature tap or drinking water (via the Flush Port)
- ✓ Failure to adequately flush the PEG tube may result in occlusion or blockage
- ✓ The stoma area should be cleansed using an aseptic technique or refer to facility procedures for stoma care
- ✓ The gastric PEG tube should be carefully moved in and out slightly in the stoma every 2–3 days once the site has healed. **Do not rotate the tube.**
- ✓ The stoma site should be clean and dry at all times.