



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?
- Do you have a good effect during the day?
(related to the continuous dose)
- How is the effect of the extra dose?

Social situation and 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?
- How is the mental situation? (depression?)
- Do you feel that you are motivated and have energy?
Has it changed over time?

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 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 it?
- 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?)

To report any side effects for Duodopa® please contact:
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National Pharmacovigilance Center Saudi Food and Drug Authority,
Fax: +966 11 205 7662
SFDA Unified Call Center: 19999
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Website: <https://ade.sfd.a.gov.sa/>

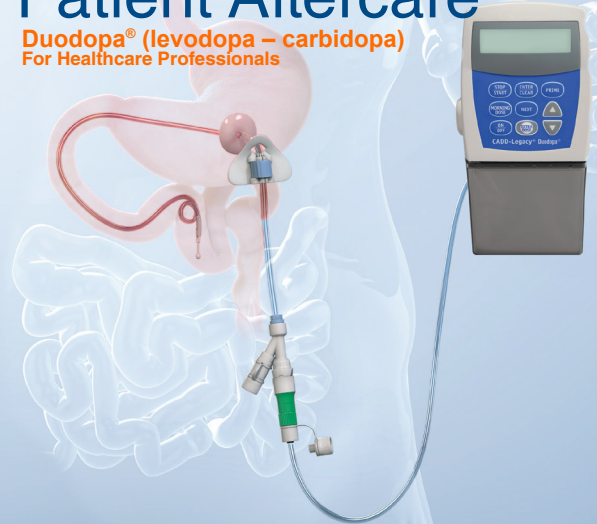
EDUCATIONAL MATERIAL FOR RISK MINIMISATION
(RISK MANAGEMENT PLAN VERSION 7.2, 13 MARCH 2017)

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Important Risk Minimisation Information

Best Practice Patient Aftercare

Duodopa® (levodopa – carbidopa)
For Healthcare Professionals



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(RISK MANAGEMENT PLAN VERSION 7.2, 13 MARCH 2017)

SA-DUOD-220001

Overview

This patient aftercare guide informs Healthcare Professionals about aftercare recommendations to minimise potential complications of PEG-J placement in patients using Duodopa® (levodopa – carbidopa intestinal gel).

Please carefully read this guide and adopt these best practices into your patient care.

Duodopa® (levodopa – carbidopa intestinal gel), 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® (levodopa – carbidopa intestinal gel), is a gel for continuous intestinal administration.

For administration of Duodopa® (levodopa – carbidopa intestinal gel) 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® (levodopa – carbidopa intestinal gel) 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® (levodopa – carbidopa intestinal gel) 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		✓



Patient At-Home Call/Visit Recommendations

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?
- Do you have a good effect of the medication during the day? (related to the continuous dose)
- How is the effect of the extra dose/How many extra dosages do you need per day?
- 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 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? (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