

DUODOPA intestinal gel▼ (co-careldopa):**ABBREVIATED PRESCRIBING INFORMATION**

Presentation: Intestinal gel containing 20mg/ml levodopa and 5mg/ml carbidopa

Basic NHS price 7 x 100ml cassettes: £539 PL 05727/0016

Legal Category: POM

Indication: Advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper/dyskinesia when available combinations of Parkinson medicinal products are unsatisfactory. A positive clinical response to Duodopa administered via a temporary nasoduodenal tube is required before a permanent tube is inserted.

Dosage and Administration: The Summary of Product Characteristics (SPC) should be read thoroughly for full prescribing information. *Adults/Elderly:* Administration by portable pump directly into the duodenum via a percutaneous endoscopic gastrostomy (PEG) or radiological gastrojejunostomy tube. Initially a nasoduodenal tube is used to determine patient's response and to adjust dose before fitting a permanent tube. Duodopa is given initially as monotherapy and dose adjusted to optimal response for the individual patient. Total dose/day is composed of three individually adjusted doses: morning bolus, continuous maintenance and extra bolus doses. Total morning dose is usually 5-10ml (100-200mg levodopa) but not exceeding 15ml (300mg levodopa). Continuous maintenance dose should be between 1-10ml/hour (20-200mg levodopa) but usually 2-6ml/hour (40-120mg levodopa/hour). Extra bolus doses (if patient becomes hypokinetic during the day) are normally 0.5-2.0ml. Increase maintenance dose if more than 5 extra bolus doses/day are needed. Fine adjustments to the morning bolus, maintenance and extra bolus doses should be made over a few weeks after the initial dose setting. Sudden deterioration in response with recurring motor fluctuations indicates the tube may have moved from the duodenum into the stomach and needs repositioning. Drug cassettes are for single use only and should not be used for longer than one day. *Children:* There is no relevant indication for use in children and adolescents.

Contraindications, Warnings etc: *Contraindications:* Hypersensitivity to ingredients, narrow-angle glaucoma, severe liver and renal insufficiency, severe heart failure or cardiac arrhythmia, acute stroke. Conditions where adrenergics are contraindicated (e.g. pheochromocytoma, hyperthyroidism, Cushing's syndrome). Non-selective MAO-inhibitors and selective MAO type A inhibitors must not be given concomitantly and should be withdrawn at least two weeks before starting Duodopa. *Warnings:* Not recommended for drug-induced extrapyramidal reactions. Caution in severe pulmonary or cardiovascular disease, bronchial asthma, renal, hepatic or endocrine disease, or history of peptic ulcer disease or of convulsions, past or current psychosis, chronic wide-angle glaucoma, co-administration with antipsychotics with dopamine receptor blocking properties or with medicines which may cause orthostatic hypotension. In patients with a history of myocardial infarction who have residual nodal or ventricular arrhythmias, cardiac function should be monitored with care during initial dose adjustments. Monitor all patients for mental changes, depression with suicidal tendencies and other serious mental changes. Neuroleptic malignant like syndrome with secondary rhabdomyolysis has not been reported with Duodopa but may occur on abrupt withdrawal. Periodically evaluate hepatic, haematopoietic, cardiovascular and renal function during extended therapy. Pathological gambling, increased libido and hypersexuality have been reported. Dose may need to be adjusted downwards to avoid levodopa induced dyskinesia. Sudden or gradual worsening of bradykinesia may indicate an obstruction in the device and should be investigated. For patients with reduced ability to handle the system, refer to full SPC. *Drug Interactions:* Antihypertensives, tricyclic antidepressants, anticholinergics, dopamine receptor antagonists, benzodiazepines, isoniazide, phenytoin, papaverine, sympathomimetics, iron, protein-rich diet. COMT inhibitors (e.g. tolcapone, entacapone) can increase the bioavailability of levodopa and amantadine acts synergistically and may increase levodopa related adverse events. Duodopa dose adjustment may be needed when used with these drugs. Duodopa can be taken with MAO type B inhibitors (e.g. selegiline) although serious orthostatic hypotension may occur.

Pregnancy and Lactation: Potential risk in pregnancy is not known. Women should not breast feed.

Ability to Drive and Operate Machinery: Caution. Refrain if somnolence or sudden sleep onset occur.

Side Effects: *Common:* Anorexia, hallucinations, confusion, nightmares, sleepiness, fatigue, sleeplessness, depression, euphoria, dementia, psychotic episodes, feeling of stimulation, dyskinesias, choreatic movements and dystonia, "ON-OFF" episodes, dizziness, palpitations, irregular heartbeat, orthostatic hypotension, fainting, syncope, nausea, vomiting, dry mouth, bitter taste. *Uncommon:* weight changes, ataxia, tremor, hypertension, hoarseness, chest pain, constipation, diarrhoea, sialorrhoea, dysphagia, flatulence, oedema, muscle spasm, dark urine, weakness, malaise, flare ups. Laboratory values may change. See SPC for details of rare and very rare side effects and for details of complications with the device.

Name and Address of Marketing Authorisation Holder:

Solvay Pharmaceuticals GmbH, Hans-Böckler-Allee 20, 30173, Hannover, Germany

Further information is available in the UK from:

Solvay Healthcare Ltd, West End, Southampton, SO18 3JD

Date of Last Review: 15 May 2008

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Solvay Healthcare.

The Parkinson's Disease Nurse Specialist Association

The Parkinson's Disease Nurse Specialist Association, [PDNSA] is a professional organisation with membership throughout the UK and overseas.

The objective of the Association is to act as a national resource and network for nurses and other healthcare professionals to share knowledge, expertise and best practice about Parkinson's disease and its management locally, nationally and internationally. It represents a body of healthcare professionals with an interest in Parkinson's and works in collaboration with the Department of Health, the Parkinson's disease society, The Royal College of Nursing, The British geriatric Society and the British and Irish Neurologists Movement disorders group.

Full membership of the PDNSA is available to Parkinson's Disease Nurse Specialists who are employed primarily in the practice of Parkinson's disease in primary and secondary care in the United Kingdom. Associate membership is open to any person who wishes to join the Association and is not eligible for full membership. Overseas Membership is open to any person who wishes to join the PDNSA and is not resident in the UK. Overseas members assume the same status as associate members. Honorary membership is awarded to individuals who have made a considerable contribution to the advancement of Parkinson's Disease Nurse Specialists. The PDNSA Committee are responsible for awarding honorary membership.

Membership entitles you to;

- 'Transmitter' our newsletter, which is published three times per year. This is an excellent forum to share best practice, experience, and inform others of current issues and developments.
- Any relevant documents published with support from the PDNSA.
- Reduced rate at our annual conference.

Professor Sir George Castledine has recently become the associations president and will be the keynote speaker at our annual conference which this year is being held on Monday 6th October and Tuesday 7th October. It is being held at the Scarman centre at Warwick University, the programme will be available very soon. The conference covers both clinical and professional issues and is an excellent opportunity for networking. We welcome new members.



To find out more about the association visit www.pdnsa.net