ROTIGOTINE Patches — Idiopathic Parkinson's disease

It is vital for safe and appropriate patient care that there is a clear understanding of where clinical and prescribing responsibility rests between Consultants and General Practitioners (GPs).
This guideline reinforces the basic premise that:
When clinical and / or prescribing responsibility for a patient is transferred from hospital to GP, the GP should have full confidence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a GP would not normally be familiar with, should not take place without the "sharing of information with the individual GP and their mutual agreement to the transfer of care."
These are not rigid guidelines. In all cases, Consultants and GPs should discuss the appropriate management of individual patients personally. On occasions, Consultants and GPs may agree to work outside of this guidance. As always, the doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Indications:	**Dosage and administration:**
The treatment of idiopathic Parkinson's disease (PD) as monotherapy (without levodopa) or as adjunct therapy (with levodopa) in patients with end of dose fluctuations.	Monotherapy – apply 2mg/24hour patch. Increase in steps of 2mg every week if required Adjunctive therapy with levodopa – apply 4mg/24hour patch. Increase in steps of 2mg every week if required Maximum dose for early stage disease is 8mg/24 hours. For advanced disease with fluctuations the maximum dose is 16mg/24 hours. Patches are replaced daily at a different site

Monitoring requirements:
Patients should be routinely seen by the consultant within one month of commencing the medication, and questioned about possible side effects such as nausea, hallucinations, postural dizziness, somnolence or increased involuntary movements. The Unified Parkinson's Disease Rating Scale (UPDRS) is a valuable tool for recording response to treatment.
There are no specific monitoring requirements. Blood pressure sitting and standing should be monitored at each visit, as there is a risk of orthostatic hypotension.

Additional information:
New patients:
Rotigotine can be used first line for patients where compliance with other oral dopamine agonists e.g. ropinirole or pramipexole is likely to be a problem or where patients have difficulty taking oral medication or are intolerant of other oral dopamine agonists.
Patients on levodopa with motor fluctuations or nocturnal distressing "off" symptoms or sleep disorder:
It can be used for patients who have developed and are distressed by motor fluctuations that may be associated with non-motor fluctuations. Other non-ergot agonists should normally be used first line, but rotigotine may be used if there are predominant nocturnal symptoms or if there is a difficulty with compliance or taking oral medication.
Peri-operative or other patients nil by mouth.
Rotigotine may be particularly useful where oral intake is impossible avoiding the necessity of giving apomorphine by injection.

Contraindications:
Rotigotine should not be given for patients with hypersensitivity, hallucinations, significant confusion, severe intolerance to dopamine agonists in general and those with hypotension (systolic blood pressure < 90 mm Hg sitting) or paroxysmal cardiac arrhythmia. Patients with severe generalised skin disorders should not receive this treatment. The dose of other dopaminergic therapy may need to be reduced as Rotigotine is introduced if the patient is suffering from excess dopaminergic side effects. It should not be given to children, adolescents or patients that may be or are pregnant.
Drug interactions:
Neuroleptics and metoclopramide should not normally be given concurrently (diminished effect of rotigotine) though quetiapine and clozapine may be given under consultant supervision in patients with features of psychosis. The effect of enzyme inducers is not known.
Cautions:
Severe hepatic impairment which reduces rotigotine clearance. Patches should be removed when entering an MRI scanner or undergoing cardioversion, as there is aluminium in the patch backing. Treatment should not be stopped suddenly to avoid neuroleptic malignant syndrome so tapering of dose should take place on withdrawal of treatment.

Adverse effects:

Dyspepsia, nausea, pain, somnolence and episodes of sudden onset of sleep, dizziness, headache and peripheral oedema are reported with rotigotine. Also rarely pathological gambling, increased libido and hypersexuality have been reported with other dopamine agonists. **Approximately 30% of patients will develop a rash at the site of the skin patches which should be rotated around different skin sites each day on a cycle of at least 14 days (abdomen, thighs, flanks, shoulders and upper arms).** Skin reactions may be severe enough to prohibit continuation of therapy and patients should be advised to avoid sunlight exposure on affected areas of skin. Patients should be warned about somnolence especially if they drive a vehicle in which case they must be warned to cease driving if they have sudden sleep attacks.

Where rotigotine is used as adjunctive therapy to levodopa, common adverse events are dyskinesia, hallucinations, dizziness, and nausea as well as local skin reactions. Depression, weight loss and anorexia are also reported in the Summary of Product Characteristics.

Ophthalmologic monitoring is recommended at regular intervals or if vision abnormalities occur.

Action to be taken if abnormal results/adverse effects:
The drug should be withdrawn if not significantly effective at relieving the patient's symptoms or if side effects develop such as increased visual hallucinations or deteriorating dyskinesias or other distressing involuntary movements occur.

Specialist responsibilities:
Diagnose condition and discuss with patient the benefits and side effects of treatment with rotigotine.
On initiation, 28 days of medication to be prescribed (using a hospital outpatient prescription form) at a recommended escalating dose as per clinical discretion, not increasing the dose more than once weekly. Most patients will respond to 6 mg daily though a lower or higher dose may be required for maximum benefit.
Review the patient's condition and initial response to treatment after one month, and if tolerating and benefiting from rotigotine at this first follow up visit a written request to be made to the GP to continue prescribing the medication. A further 28 days supply of medication should be prescribed (using a hospital outpatient prescription form).
Regularly review the patient's condition and monitor response to treatment.
Communicate promptly with GP when treatment is changed.
Advise GPs when to refer back and when and how to stop treatment (see section above and secondary care review section below).
Report adverse events to the CSM.
Ensure that clear backup arrangements exist for GPs for advice and support.

GP's responsibilities:
Reply to the request for shared care as soon as practicable.
Prescribe rotigotine.
Monitor patient's response to treatment.
Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
Refer back to specialist if condition deteriorates, as advised.
Report adverse events to specialist and CSM.
Stop treatment on advice of specialist.

Patient's responsibilities:
Report to the specialist or GP if he or she does not have a clear understanding of the treatment or has concerns in relation to treatment with rotigotine
Report any adverse effects to the specialist or GP whilst taking rotigotine.

Secondary care review:
Every six months in movement disorder clinic. Where there is a specific problem, patient may be seen in the community by Parkinson's disease specialist nurse (if appropriate) or return earlier to clinic for review.

Availability:
Rotigotine patches releasing 1mg/24 hrs, 2mg/24 hrs, 3mg/24 hrs, 4mg/24 hrs, 6mg/24 hrs, 8mg/24 hrs in packs of 28.

Back up advice and support:	**Telephone**
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