Dorset Medicines Advisory Group

# SHARED CARE GUIDELINES FOR PRESCRIBING RASAGILINE IN PARKINSON'S DISEASE

## INDICATION

Rasagiline is a monoamine-oxidase-B-inhibitor indicated for 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.
NICE states that MAO-B inhibitors should not be used as neuro-protective therapies (CG 35).

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## AREAS OF RESPONSIBILITY FOR SHARED CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of rasagiline can be shared between the specialist setting and the patient's GP. GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

## REFERRAL AND INITIATION

The diagnosis of Parkinson's disease will be undertaken by a consultant and their team. Pharmacological measures should not be initiated prior to specialist referral. In some cases it may not be appropriate to initiate therapy with rasagiline when the patient is seen by the specialist team. It may therefore be necessary for GPs to initiate therapy where a delay in initiation is required.

| **Specialist Responsibilities** | |
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| 1 | To assess the patient and establish the diagnosis, determine a management strategy and ensure appropriate follow-up in conjunction with the GP. |
| 2 | Where appropriate:<br>• to initiate and stabilise treatment;<br>• To discuss with the patient the benefits and side effects of treatment with rasagiline.<br>• obtain consent from the patient's GP to continue prescribing once treatment has been stabilised (usually after 4 weeks) or if a delay in initiation is required to obtain their consent to start treatment when indicated<br>• to review the patient's condition and initial response to treatment after one month, and if tolerating and benefiting from rasagiline at this first follow up visit, a request to be made to the GP to continue prescribing the medication<br>• Monitor the patient and their therapy at six monthly intervals. |
| 3 | To provide the GP with appropriate prescribing information and any additional information requested. |
| 4 | To be available for advice if the patient's condition changes. |
| 5 | To ensure that procedures are in place for the rapid re-referral of the patient by the GP. |
| 6 | To ensure the patient has given informed consent to their treatment. |
| 7 | To liaise with the GP on any suggested changes in prescribed therapy. |

| General Practitioner Responsibilities | |
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| 1 | Initially, to refer the patient for specialist advice. |
| 2 | Where appropriate to continue to prescribe rasagiline as part of a shared care arrangement (usually after 4 weeks). If a decision has been made to delay initiation GPs may initiate therapy in accordance with the specialist's instructions. |
| 3 | To deal with general health issues of the patient. |
| 4 | Monitor response and concordance with therapy |
| 5 | 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. |
| 6 | Report adverse events to specialist and CSM |
| 7 | Stop treatment or make changes to therapy on advice of specialist. |

| Patient's role (or that of carer) | |
|---|---|
| 1 | Report to the specialist or GP if he or she does not have a clear understanding of the treatment |
| 2 | Report any adverse effects to the specialist or GP whilst taking rasagiline |
| 3 | Attend appropriate GP and other follow up appointments |
| 4 | Share any concerns in relation to treatment with the rasagiline |
| 5 | Use written and other information on the medication. |
| 6 | Seek help urgently if suspect side effects, or otherwise unwell. |

## SUPPORTING INFORMATION

### Dosage and Administration

Dose of 1 mg once daily with or without levodopa. It may be taken with or without food. Unless more urgent circumstances so dictate, treatment should only be stopped on the advice of a specialist.

### Additional information:

New patients: Selegiline should normally be used first line, but rasagiline can be used if selegiline has not been tolerated, or is contraindicated because of symptomatic postural hypotension (>20mm Hg drop in systolic pressure 1-3 minutes after an active stand from lying, after resting for 5 minutes). It can be used where patients have expressed a preference for once daily medication, or where compliance can be improved.

Patients on levodopa with motor fluctuations: It can be used for patients who have developed and are distressed by motor fluctuations that may be associated with non-motor fluctuations where the patient has been intolerant to entacapone or dopamine agonists or where these drugs are contraindicated. Selegiline should normally be used first line, but rasagiline can be used if selegiline has not been tolerated.

It can be used where patients have expressed a preference for once daily medication, or where compliance can be improved, or where the patient has been intolerant of entacapone or dopamine agonists or where these drugs are contraindicated.

### Monitoring

Patients should be reviewed by the specialist within one month of commencing the medication, and questioned about possible side effects such as joint pain, flu like syndrome, hallucinations, postural dizziness or increased involuntary movements. Response to treatment will also be determined. A useful tool to achieve this is the Unified Parkinson's Disease Rating Scale (UPDRS). There are no specific monitoring requirements.

**Contraindications**

Rasagiline should not be given to patients with severe hepatic failure (with an albumin of <25 g/l or encephalopathy or bilirubin > 200 µmol/l.)

Hypersensitivity to the active substance or to any of the excipients in the product

Concomitant treatment with other monoamine oxidase (MAO) inhibitors (including medicinal and natural products without prescription e.g. St. John's Wort) or pethidine At least 14 days must elapse between discontinuation of rasagiline and initiation of treatment with MAO inhibitors or pethidine.

**Cautions**

Caution should be used when initiating treatment in patients with mild hepatic insufficiency. Rasagiline use in patients with moderate hepatic impairment should be avoided. If patients progress from mild to moderate hepatic impairment, rasagiline should be stopped.

Concomittant use of potent CYP1A2 inhibitors e.g. ciprofloxacin may increase the plasma levels of rasagiline and should be used with caution. There is a risk that the plasma levels of rasagiline in smoking patients could be decreased, due to induction of the metabolising enzyme CYP1A2. Patients taking rasagiline who stop smoking should be monitored for increased side effects.

Rasagiline should be avoided if there is a history of visual hallucinations.

**Side effects**

Headache, depression, dyspepsia, nausea, pain and dizziness are commonly reported with rasagiline as monotherapy.

Where rasagiline is used as adjunctive therapy to levodopa, common adverse events are dyskinesia, hallucinations, sleep disorder, dizziness, and nausea.

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.

Depression, weight loss and anorexia are also reported in the Summary of Product Characteristics.

**Interactions**

Rasagiline should not be co-administered with: pethidine, fluoxetine, fluvoxamine, or monoamine oxidase inhibitor antidepressants

Concomitant administration of rasagiline with all other antidepressants (risk of CNS toxicity with SSRI's and tricyclics) or entacapone (reduced plasma concentration of rasagiline) should be carried out with additional caution and close observation reviewing the patient within 1 week of commencement.

Patients should not concomitantly use dextromethorphan, sympathomimetic nasal decongestants or cold medications containing ephedrine or pseudoephedrine

**This list is not exhaustive. The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contra-indications, warnings, side-effects and drug interactions.**

**Drug costs:**

Rasagiline 1mg tablets x 28 £39.15 Drug Tariff September 2016

**References**

Azilect 1mg Tablets Summary of Product Characteristics. Teva Pharmaceuticals Ltd. Last Updated 08-Jun-2016. Accessed 2/7/16 http://www.medicines.org.uk/emc/medicine/16273

NICE. Clinical Guideline– Parkinson's disease: diagnosis and management in primary and secondary care (June 2006): www.nice.org.uk/CG035

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