

Name: Attach Banda Label here
 Address:
 Date of Birth:
 NHS number:



Rivastigmine: for the treatment of Dementia associated with Parkinson's disease

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Rivastigmine for Dementia in Parkinson's disease can be shared between the specialist and general practitioner (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 between the specialist, GP and patient. The intention to share care is usually explained to the patient by the specialist 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.

Specialist Responsibilities

1. Undertake assessment to diagnose dementia associated with Parkinson's disease.
2. Counsel patient and carers about the implications of the diagnosis, likely effects of medication and treatment endpoints. Provide written information on the medication.
3. Initiate and stabilise treatment with Rivastigmine for dementia associated with Parkinson's disease. When using assessment scales to determine the severity of cognitive impairment, any ethnic, cultural, physical, sensory or learning disabilities should be accounted for and the results adjusted accordingly. Health care professionals should not rely solely on cognition scores when it is inappropriate to do so.
4. Ask the GP whether he or she is willing to participate in shared care by faxing the template letter
5. Continue to prescribe until the GP has agreed to take over prescribing
6. Communicate to the GP re-established regimen and when to refer back
7. Monitor treatment as stated overleaf
8. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of adverse effects or deteriorating clinical condition (i.e. via normal referral protocol)
9. Review patient as stated overleaf – cognitive, global, functional and behavioural assessment, communicating the results to the GP
10. Seek the carer's views on the condition of the patient at baseline and at follow-up.
11. Assess the point at which treatment is no longer beneficial. Treatment should be continued only when it is considered to be having a worthwhile effect on cognitive, global functional or behavioural symptoms. Arrange to monitor the clinical effects of gradual withdrawal of the medication
12. Report adverse events to the MHRA on a Yellow Card www.mhra.gov.uk/yellowcard, and to the GP and appropriate Medicines Management team
13. Ensure that clear back-up arrangements exist for GPs to obtain advice and support

General Practitioner Responsibilities

1. Reply to the request for shared care as soon as practicable by faxing back signed form
2. Prescribe rivastigmine at the dose recommended
3. Adjust the dose as advised by the specialist
4. Monitor treatment as stated overleaf
5. Report and seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment
6. Refer back to specialist if the patient's condition significantly deteriorates or if there are concerns over patient compliance
7. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises
8. Report adverse events to the MHRA on a Yellow Card (www.mhra.gov.uk/yellowcard), the specialist, and the appropriate Medicines Management team.

Patient/carer's role

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with rivastigmine.
3. Inform specialist or GP of any other medication being taken including over-the-counter products.
4. Report any adverse effects to the specialist or GP whilst taking rivastigmine.
5. Alert GP or specialist of any changes in circumstances that could affect drug treatment.
6. Report any adverse effects or warning symptoms to the specialist or GP. The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card, available at pharmacies, GP surgeries or from the Yellow Card hotline (freephone 0808 100 3352 during business hours). The form can also be downloaded from www.mhra.gov.uk/yellowcard.

BACK-UP ADVICE AND SUPPORT: See patient letter

This SCA should be read in conjunction with the Summary of Product Characteristics (SPC) and the current edition of the British National Formulary

SUPPORTING INFORMATION:

Licensed indications: Rivastigmine is licensed for the symptomatic treatment of mild to moderately severe dementia associated with Parkinson's disease. Only specialists in the care of dementia in Parkinson's disease should initiate treatment. Treatment should be continued only when it is considered to be having a worthwhile effect on cognitive, global, functional or behavioural symptoms.

Dosage and administration: See CG027 on Drugs for Dementia: Cost Effective Formulations

Rivastigmine: 1.5mg twice daily, with the morning and evening meals; increased in steps of 1.5mg twice daily at intervals of at least 2 weeks up to a maximum of 6mg twice daily. Re-titration from 1.5mg twice daily should be undertaken if treatment is interrupted for more than several days.

Monitoring:

Specialist team: Monitor for effectiveness at least once every 12 months (using cognitive, global, functional and behavioural assessment) as clinically appropriate. Monitor for weight loss or symptoms of peptic ulcer disease or gastrointestinal bleeding when conducting patient reviews. Patients at increased risk for developing ulcers include those with a history of ulcer disease or those receiving medicines which will increase risk of bleeding e.g. nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, anticoagulants, selective serotonin reuptake inhibitors (SSRIs).

GP: Cholinesterase inhibitors have been associated with weight loss. GPs should be mindful of the potential for weight loss or symptoms of peptic ulcer disease or gastrointestinal bleeding when conducting patient reviews. Patients at increased risk for developing ulcers include those with a history of ulcer disease or those receiving medicines which will increase risk of bleeding e.g. nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, anticoagulants, selective serotonin reuptake inhibitors (SSRIs). Contact the specialist team between specialist's yearly reviews if there are any concerns which may need earlier attention.

Cautions: Rivastigmine is cautioned in: cardiovascular disease, severe asthma, obstructive pulmonary disease or active pulmonary infections, people at increased risk of developing peptic ulcers. It may exacerbate/induce extrapyramidal symptoms. Caution is recommended when selecting neuromuscular blocking agents with anaesthesia.

Dose titration: Adverse reactions (e.g. hypertension and hallucinations in patients with Alzheimer's dementia and worsening of extrapyramidal symptoms, in particular tremor, in patients with dementia associated with Parkinson's disease) have been observed shortly after dose increase. They may respond to a dose reduction.

Contra-indications: Rivastigmine is contra-indicated where there is hypersensitivity to the active substance or any of the excipients. Contra-indicated in patients with a known hypersensitivity to carbamate derivatives or in those with severe liver impairment.

Side effects (see SPC for full details): Nausea, vomiting, diarrhoea, fatigue, insomnia, dyspepsia, anorexia, abdominal pain, dizziness, headache, drowsiness, tremor, asthenia, malaise, agitation, confusion; sweating; weight loss; less commonly gastric or duodenal ulceration, bradycardia, syncope, depression, insomnia; rarely angina pectoris, seizures; very rarely gastro-intestinal haemorrhage, pancreatitis, cardiac arrhythmias, hypertension, hallucinations, extrapyramidal symptoms (including worsening of Parkinson's disease), rash.

Drug interactions (see also above under cautions): May interact with medications having anticholinergic activity or drugs that have effects on cardiac conduction e.g. beta blockers. Rivastigmine should not be given with other cholinomimetics (e.g. neostigmine, pyridostigmine, bethanecol). May show increased muscle relaxation when given with agents such as succinylcholine or other neuromuscular blocking agents. Rivastigmine may inhibit the butyrylcholinesterase mediated metabolism of other substances.

Cost (Drug Tariff Dec 2019): At current prices, one year's treatment will cost £6.04 for 3 mg PO twice a day.

References:

1. Joint Formulary Committee. *British National Formulary*. [72] ed. London: BMJ Group and Pharmaceutical Press; [Sept 2016]
2. Electronic Medicines Compendium. Rivastigmine Activis 1.5mg, 3mg, 4.5mg, and 6mg hard capsules. [Jan 2016]
3. Coventry and Warwickshire APC: CG027 on Drugs for Dementia: Cost Effective Formulations