

SHARED CARE PRESCRIBING GUIDELINE

**RIVASTIGMINE for the Treatment of BEHAVIORAL PROBLEMS
 AND PSYCHOSIS IN PARKINSON'S DISEASE DEMENTIA
 COMPLEX (PDDC)**

Frimley Park Hospital's classification: Amber

N.B. The eligibility criteria included here apply to new patients commencing treatment under this guideline & not to existing patients whose treatment was initiated under the previous version. However, monitoring and discontinuation criteria apply to all patients.

NOTES to the GP

Amber drugs: Prescribing to be initiated by a hospital specialist (or if appropriate by a GP with specialist interest) but with the potential to transfer to primary care. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs.

The questions below will help you confirm this:

- Is the patient's condition predictable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility. Sign and return a copy of page 4 to the requesting consultant at the Acute Trust. Until the requesting consultant at the Acute Trust has received a signed copy of page 4 indicating that shared care has been agreed all care (including prescribing) remains with the consultant at the Acute Trust.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your PCT pharmacist will assist you in making decisions about shared care.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

The patient's best interests are always paramount

The GP has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant

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|--------------------------|---------------------------|------------------------------------|
| Reason for Update: New | | Prepared by: J Buckland, Dr Stern |
| Valid from: January 2009 | Review date: January 2011 | Approved by: Prescribing Forum FPH |
| Version: 0.1 | Supersedes version: NA | Approved by: NA |

Information

In Frimley Park Hospital rivastigmine is available to be prescribed for patients with PDDC, in line with NICE guidance on Parkinson's disease (Clinical Guideline 35, June 2006). Traditionally, dementia developing more than 1 year after the onset of the motor features of PD is referred to as PD with dementia (PDD). Dementia developing within 1 year of the onset of motor features is classified as dementia with Lewy bodies. The relationship between PDD and dementia with Lewy bodies is unclear, but many consider them to be a continuum rather than discrete entities.

There is evidence from randomised placebo-controlled trials of the effectiveness and safety of cholinesterase inhibitors in the treatment of PDD. They are effective in treating both cognitive decline and psychosis in this context. In addition, rivastigmine produces clinically significant improvements in behavioral symptoms and cognitive function, with fewer delusions and hallucinations. However, not all patients respond, so regular review of the need for these agents is required. At the time of writing, only one of the cholinesterase inhibitors (rivastigmine) has a product license for this indication. The NICE guideline considers that these are useful agents, commonly used in clinical practice and that they should be available to patients.

This information sheet does not replace the SPC, which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

Link to the relevant SPC website: www.medicines.org.uk

Dose

Starting dose: 1.5mg twice daily
Maintenance dose range: 3-6mg twice daily
Maximum dose: 6mg twice daily.

Cautions

Sick sinus syndrome or other supraventricular cardiac conduction conditions
Susceptibility to peptic ulcers, asthma, COPD
Patients predisposed to urinary obstruction
Extrapyramidal symptoms may be exacerbated by rivastigmine.

Contraindications

Known hypersensitivity to rivastigmine hydrochloride, other carbamate derivatives, or to any excipients used in the formulation.
Severe liver impairment

Side effects

Very Common (>10%): Nausea, vomiting.

Common (1 –10%): Dizziness, fatigue, somnolence, insomnia, depression, headache, tremor, syncope, asthenia, diarrhoea, abdominal pain, dyspepsia, fever, malaise, anorexia, weight loss, fall, injury.

Interactions

Rivastigmine should not be given concomitantly with other cholinomimetic drugs and might interfere with the activity of anticholinergic medications.

No pharmacokinetic interaction was observed between rivastigmine and digoxin, warfarin, diazepam or fluoxetine in studies in healthy volunteers.

Criteria for Use

RESPONSIBILITIES and ROLES

| Specialist responsibilities | |
|------------------------------------|---|
| 1 | Provide a diagnosis |
| 2 | Initiate treatment for the management of PDDC |
| 3 | Discuss benefits and side effects of treatment with the patient and carer |
| 4 | Ensure that the patient/carer realises treatment will be stopped if no convincing evidence of benefit on review |
| 5 | Ensure baseline monitoring as appropriate. |
| 6 | Initiate treatment taking into account contra-indications, cautions, side-effects, compliance issues and cost. |
| 7 | Establish the patient on a stable dose of rivastigmine or the first month of treatment. |
| 8 | Be alert to inducing drug interactions |
| 9 | Monitor patient response and assess for adverse effects |
| 10 | Review the patient according to clinical need and NICE guidance |
| 11 | Communicate promptly with the GP any changes in treatment |
| 12 | Continue treatment only while there is evidence of worthwhile benefit |
| 13 | Advise GP on when and how to discontinue treatment (if necessary), and provide any required supervision. |
| 14 | Explain to the patient / carer their roles |

| General Practitioner responsibilities | |
|--|---|
| 1 | Subsequent prescribing of rivastigmine at the dose recommended. |
| 2 | Report to and seek advice from the PD Specialist on any aspect of patient care that is of concern to the GP and may affect treatment. |
| 3 | Communicate promptly to the PD Specialist any changes to treatment made by the GP. |
| 4 | Discontinue treatment (if necessary) on the advice of the PD specialist |
| 5 | Be alert to inducing drug interactions |
| 6 | Monitor for adverse effects and inform the specialist as appropriate. |
| 7 | Report any concerns regarding non-adherence with treatment to the specialist |

| Monitoring requirements and appropriate dose adjustments (if relevant to specific drug) | |
|--|---------------|
| 1 | None required |
| 2 | |
| 3 | |

| Patient's / Carer's role | |
|---------------------------------|---|
| 1 | Ask the specialist or GP for information, if he or she does not have a clear understanding of the treatment. |
| 2 | Share any concerns in relation to treatment with rivastigmine |
| 3 | Tell the specialist or GP of any other medication being taken, including over-the-counter products. |
| 4 | Read the patient information leaflet included with your medication and report any side effects or concerns you have to the specialist or GP |

BACK-UP ADVICE AND SUPPORT

| Contact details | Specialist | Telephone No. | Email address: |
|---------------------------|---------------------|----------------------|----------------|
| Specialist: | Dr Stern | 01276 604 148 | |
| | Dr Wren | 01276 604 544 | |
| | Dr Munim | 01276 604 693 | |
| | Dr Debrah | 01276 604 027 | |
| | Dr Naidoo | 01276 604 085 | |
| Hospital Pharmacy: | Jacqueline Buckland | 01276 604 723 | |

AUDIT / SURVEY (to be carried out by specialist clinic)

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RIVASTIGMINE for the Treatment of BEHAVIORAL PROBLEMS AND PSYCHOSIS IN PARKINSON'S DISEASE DEMENTIA COMPLEX (PDDC)

Agreement for transfer of prescribing to GP

Patient details / addressograph:

Name.....

Address.....
.....
.....

DOB.....

Hospital No.....

Drug name and dose:

The following tests, investigations have been carried out:

Date initiated:.....

At the last patient review the drug appeared to be effectively controlling symptoms/ providing benefit:
Yes / No

The patients has now been stabilised on a dose of:

I will arrange to review this patient regularly. Date of next clinic appointment:.....

Consultant:

Address:

Contact Number

GP:

Address:

Contact Number

Main Carer:

Contact Number:

Key worker if appropriate:

Contact Number:

Agreement to shared care, to be signed by GP and Consultant.

Consultant Signature:

.....
Date:

GP Signature:

.....
Date:

If shared care is agreed and GP has signed above please return a copy of this page to the requesting consultant or alternatively fax to:
Acute Trust please insert appropriate Fax Number: