

SHARED CARE PRESCRIBING GUIDELINE

RILUZOLE for the Treatment of MOTOR NEURONE DISEASE

Frimley Park Hospital's Prescribing Forum 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

Reason for Update: Review		Prepared by: J Buckland & Dr J Stern
Valid from: January 2009	Review date: January 2011	Approved by: Prescribing Forum FPH
Version: 2	Supersedes version: 1	Approved by: Prescribing Forum, FPH

Information

Excessive stimulation of glutamate receptors may cause or play an important role in the destruction of motor neurones in motor neurone disease. *In vitro* riluzole inhibits the release of glutamate, thereby decreasing the firing of motor neurones induced by glutamate receptor agonists thus protecting cells from glutamate-mediated damage.

A Cochrane review (2002 Issue 4) concluded that riluzole probably prolongs survival by approximately two months.

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

50mg twice daily orally

If patients are unable to swallow tablets, the tablets may be crushed for administration via a PEG or nasogastric tube or mixed with a soft food product.

Cautions

History of abnormal hepatic function

Contraindications

Severe hypersensitivity to riluzole or any of the excipients

Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal

Patients who are pregnant or lactating

Side effects

Asthenia, nausea, headache, abdominal pain, pain, vomiting, dizziness, tachycardia, somnolence, circumoral paraesthesia, deranged LFTs, neutropenia, anaphylactoid reaction, angioedema, pancreatitis

Interactions

Riluzole is metabolized by CYP1A2 hence potential for CYP1A2 interactions. The clinical significance has not been established.

- Inhibitors of CYP1A2 - cimetidine, macrolide and quinolone antibiotics
- Inducers of CYP1A2 - rifampicin
- Drugs metabolised by CYP1A2 - warfarin, verapamil, theophylline, tricyclic antidepressants

Criteria for Use

RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	Diagnosis of Motor Neurone Disease and assessment of suitability of patients for riluzole treatment
2	To initiate therapy by prescribing and supplying the first months treatment
3	Liaison with the GP to agree to share the patient's care
4	To monitor and evaluate response to riluzole therapy and decide in conjunction with the patient and all medical attendants on discontinuation
5	To monitor and evaluate adverse drug reactions
6	Explain to the patient / carer their roles

General Practitioner responsibilities	
1	Subsequent prescribing of riluzole at the dose recommended.
2	To inform the Neurology team of changes in the patient's condition which may be related to riluzole
3	To monitor riluzole as described below

Monitoring requirements and appropriate dose adjustments (if relevant to specific drug)	
1	Check ALT monthly for the first three months every 3 months for the next nine months and then every 6 months thereafter Stop if ALT is greater than five times upper limit of normal
2	Check renal function every 6 months Manufacturers do not have data and therefore cannot recommend use in renally impaired patients: risk/benefit to be considered
4	Check white blood cell counts in febrile illness and to stop riluzole if the patient is found to be neutropenic Stop if neutropenic ($<1 \times 10^9$ /L)

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 riluzole
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 J Stern Dr D Wren	01276 604 148 01276 604 544	
Hospital Pharmacy:	J Buckland	01276 604 723	Jacqueline.kew@fph-tr.nhs.uk

AUDIT / SURVEY

None listed

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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:

List any relevant tests: LFTs

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: