Barts Health NHS Trust

Shared Care Guideline for Motor Neurone Disease

Riluzole

Executive Summary/ Critical Information.

Indication	Route & Dose	Key aims of treatment in the long term	Monitoring undertaken by specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Duration of treatment	Stopping criteria	Follow up (weeks/months)
Motor Neurone Disease	Riluzole 50mg twice a day	To extend life or the time to mechanical ventilation by two to four months (as evidenced by two trials evaluated in the NICE TA 20) for patients with amyotrophic lateral sclerosis (ALS).	Full blood count: differential WBC and serum ALT	Serum Alanine Transaminase (ALT) Monthly for the first three months then three monthly thereafter for 9 months. Subsequently, period testing should occur with increased frequency for patients who develop raised levels of ALT. White blood cells counts (WBC) Monthly for the first three months.	Usually up to 3 years	Disease progression. Toxicity/adverse effects: neutropenia <1.0 x10^9/L or , ALT levels increase to five times the upper limit of the normal range (ULN)	Specialist - For the first 3 months the patient will be seen in secondary care, once the patient is deemed to be stable with no side-effects they will transfer to primary care. GP – Monitor bloods every month for first three months and then every three months for 9 months then periodically.

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Key Safety Notice (for instance: notification if prescribing must be brand specific or BNF cautionary and advisory warnings).
Riluzole can be prescribed as the generic, with orodispersible films and the liquid preparation used for patients with swallowing difficulties.

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1. **Background**

   Riluzole is used to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis. NICE guidance, (number 20, January 2001), recommends that riluzole should be made available for the treatment of individuals with the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease.

   Riluzole is not licensed for other forms of MND, but patients with progressive bulbar palsy (PBP) are considered by NICE to have a form of ALS, and are also eligible for treatment with riluzole.

   Riluzole therapy is initiated by a neurological specialist with expertise in the management of MND. The benefit v's risk to extend life or the time to mechanical ventilation for patients with ALS has been conducted by the specialist neurologist for the groups of patients who may potentially benefit from this treatment.

   Routine supervision of therapy should be managed as indicated in this shared care guideline.

2. **Important information**

   Riluzole should be initiated by a consultant after baseline tests. Further monitoring is outlined below.

3. **Drug name, form, and licensed indications (unlicensed/off-label)**

   Riluzole is available as 50mg film coated tablets (generic available), riluzole orodispersible films and riluzole oral suspension (5mg/ml).

4. **Dose and Administration**

   Adult dosage:
   Recommended daily dose in adults and the elderly is 50mg twice daily (every 12 hours) with no significant benefit in increasing the dose further.

   The orodispersible films and oral suspension may be used in primary care, on hospital recommendation for patients unable to take solid formulation. Riluzole orodispersible films and oral suspension should be used as the first line option, although tablets may be crushed (if necessary) immediately prior to administration (unlicensed use).

   The orodispersible films should only be handled with clean dry hands and should not be folded. They should not be taken with liquids or chewed and whilst the film dissolves the patient should avoid talking. Food or other medication should be taken with caution after administration due to the local anaesthetic effect (slight numbing of mouth). After administration hand should be washed.

   If administration of the liquid if via the nasogastric tube (NG) or percutaneous endoscopic gastrostomy (PEG), then the tube should be flushed with 10ml of water after each dose to ensure the dose has been pushed through the line. If NG feeds are used, there should preferably be a break in feed administration.

5. **Contraindications/Cautions**

   Caution should be had with patients who have a:

   - history of abnormal liver function or slightly elevated serum transaminases up to 3x the upper limit of normal.
   - Febrile illness or neutropenia

   Contraindications:

   - Hepatic disease or where baseline transaminases (ALT) are greater than three times the upper limit of normal
   - Patients with baseline elevations of several liver-related biochemical parameters (especially bilirubin)
   - Interstitial lung disease

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- Pregnancy
- Breastfeeding
- Hypersensitivity to riluzole or any tablet excipients

For complete list of contraindications and cautions, please refer to the SPC: https://www.medicines.org.uk/emc.

6. Drug interactions

Potential interactions may occur with the following:

- Enzyme Inhibitors – may decrease the rate of riluzole elimination
  - Caffeine
  - Diclofenac
  - Diazepam
  - Theophylline
  - Tricyclic antidepressants eg amitriptyline, imipramine, clomipramine
  - Macrolides eg erythromycin, clarithromycin
  - Quinolones eg ciprofloxacin, ofloxacin
  - Fluvoxamine
- Enzyme Inducers – may increase the rate of riluzole eliminations
  - Chronic smoking / cigarette use
  - Omeprazole
  - Rifampicin

For complete list of drug interactions, please refer to the SPC: https://www.medicines.org.uk/emc.

7. Side effects which require managing

Riluzole should be discontinued if, during treatment, ALT levels increase to five times the upper limit of the normal range (ULN). Where this occurs, re-starting riluzole is not recommended and the hospital consultant should be contacted

Where there is evidence of febrile illness / neutropenia (<1.0 x 10^9/L), the patient should seek immediate medical attention. White cell counts should then be determined. If evidence of neutropenia, riluzole should be discontinued and the hospital consultant contacted.

For complete list of side effects, please refer to the SPC: https://www.medicines.org.uk/emc.

8. Process for Referral Back to Secondary Care

If a GP has taken blood tests for the general management of a patient and the ALT has increased to five times the upper limit of normal, the patient should be informed to stop riluzole and the hospital consultant contacted. This can be done via the MND co-ordinator on email: colettebloomfield@nhs.net or via the contacts listed below.

9. Monitoring and Responsibilities

Pre initiation of therapy (baseline):

Parameter	**Responsibility for monitoring**
Full blood count (particularly WBC) and serum ALT	Consultant initiating therapy

During therapy:
GPs are responsible for the monitoring below and should take action as indicated. They should contact the hospital consultant to discuss any concerns.

Parameter	Frequency	Action in response to abnormal result	Responsibility for monitoring
Serum Alanine Transaminase (ALT)	Monthly for the first three months then three monthly thereafter for 9 months. Subsequently, period testing should occur with increased frequency for patients who develop raised levels of ALT.	Riluzole should be discontinued if, during treatment, ALT levels increase to five times the upper limit of the normal range (ULN). Where this occurs, re-starting riluzole is not recommended and the hospital consultant should be contacted	GP
White blood cells counts (WBC)	Monthly for the first three months	Where there is evidence of febrile illness / neutropenia the patient should seek immediate medical attention. White cell counts should then be determined. If evidence of neutropenia, riluzole should be discontinued and the hospital consultant contacted.	GP

a. Hospital specialist:
- Send a letter to the GP requesting shared care for the patient
- Prescribe the first three months of medication
- Routine clinic follow up on a regular basis
- Inform the GP after each clinic attendance if there is any change to treatment or monitoring
- Evaluation of any reported adverse effects by GP or patient
- Inform GP of patients who do not attend clinic appointments
- To provide any advice to the patient/carer when requested
- Ensure that backup advice is available at all times

b. General Practitioner:
- Agreement to shared care guideline by the GP
- Report any adverse events to the hospital specialist, where appropriate
- Request advice from the hospital specialist when necessary
- Monitor patient's overall health and wellbeing
- Prescribe the drug treatment as described
- Monitor the blood results as above
- Help in monitoring the progression of the disease

c. Patient or parent/carer:
- Patient must not exceed prescribed dose

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- Patients must attend their scheduled clinic and blood test appointments
- Must inform other clinical staff that they are receiving treatment
- Report any adverse effects to the hospital specialist and GP
- Discuss potential benefits and side effects of treatment with the specialist and GP, to identify whether they have a clear picture of these from the specialist and to raise any outstanding queries

10. Contact Information

Main switchboard: 02073777000
Consultant Secretary: 020-35941202, forem.khilochia@nhs.net
MND Co-ordinator: 07825-935187, colettebloomfield@nhs.net
Neurology Registrar on-call out of hours – Aircall via switchboard

11. References

a. Guidance on the use of Riluzole (Rilutek) for the treatment of Motor Neurone Disease Published January 2001
b. Medicines.org.uk (2019) Rilutek- Summary of Product Characteristics (SPC) – (eMC) – [online]
c. Medicines.org.uk (2024) Emylif - Summary of Product Characteristics (SPC) – (eMC) – [online]

12. Document Management

Document ratification and history	
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Appendix 1.

Shared Care Guideline: Prescribing Agreement	
Section A: To be completed by the hospital consultant initiating the treatment	
GP Practice Details: Name: Tel No: Email (nhs.net):	**Patient Details:** Name: DOB: NHS Number (10 digits):
Consultant Details: Consultant Name: Secretary Contact Details: Tel No: Email (nhs.net):	
Diagnosis:	**Drug Name (to be prescribed by GP):** **Dose:** **Frequency:**
I will review the patient in clinic in weeks / months (*Delete as appropriate)*.	

Dear

Your patient started treatment with the above drug for the above diagnosis on (insert date) and in my view; his/her condition is now stable.

The patient has given consent to treatment under a shared care prescribing agreement and has agreed to comply with instructions and follow up requirements.

I am requesting your agreement to sharing the care of this patient from (insert date) in accordance with the attached Shared Care Prescribing Guideline.

This patient was reviewed on (insert date). These are the results relevant for the drug and/or condition, as outlined in the shared care document:

Test	Baseline	Date

Please continue to monitor the patient as outlined in the shared care guidelines. Refer to the attached guidelines for monitoring criteria.

Other relevant information:

Consultant Signature:	Date:

Section B: To be completed by the GP and returned to the hospital consultant as detailed in Section A above [If returned via e-mail, use NHS.net email account ONLY]

Please sign and return your agreement to shared care within 14 days of receiving this request.

☐ Yes, I accept sharing care as per shared care prescribing guideline.

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☐ No, I am not willing to undertake shared care for this patient for the following reason: (Please give reason)		
GP Name:	GP Signature:	Date:

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