

**THE SHEFFIELD AREA PRESCRIBING GROUP**

# **Shared Care Guideline**

**For**

**Riluzole**

**Shared care guideline developed by:**

**Sharron Kebell, Specialised Commissioning Pharmacist,  
Sheffield CCG**

**Ben Dorward, Lead Neurosciences Pharmacist, STH**

**Professor Chris McDermott, Consultant Neurologist, STH**

**Theresa Walsh, Motor Neurone Disease Specialist Nurse, STH**

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**Review Date: 3 years from approval**

# Riluzole Shared Care Guideline

## Statement of Purpose

This shared care guideline has been written to enable the continuation of care by primary care clinicians of adult patients initiated and stabilised on riluzole by neurologists at STH. Primary care will only be requested to take over prescribing of riluzole within its licensed indication unless specifically detailed otherwise below.

## Indication

Motor neurone disease is the term used to describe progressive muscular atrophy (PMA) and amyotrophic lateral sclerosis (ALS) which includes Progressive Bulbar Palsy.

ALS, which is characterised by both upper and lower motor neurone signs, is the most common form of MND, accounting for 65% to 85% of all cases. Adult-onset MND is characterised by progressive degeneration of the motor neurones of the brain, brain stem or spinal cord, starting insidiously with symptoms and signs including stumbling, foot drop, weakened grip, slurred speech, cramp, muscle wasting, twitching and tiredness. Other symptoms of MND include muscle stiffness, paralysis, incoordination and impaired speech, swallowing and breathing. Most individuals die from ventilatory failure, resulting from progressive weakness and wasting of limb, respiratory and bulbar muscles within approximately 3 years of the onset of symptoms.

Riluzole is licensed to extend life or the time to mechanical ventilation for individuals with the amyotrophic lateral sclerosis (ALS) form of motor neurone disease (MND)

## Selection of patients

Patients will be: diagnosed; assessed for suitability of treatment with riluzole; have benefits and side effects discussed; will have treatment initiated and have baseline and initial monitoring done by neurologists.

Patients will only be transferred to the primary care clinician on confirmation that liver function tests (LFTs) are within the normal range at month 3.

## Dosage

### 50mg every 12 hours

#### Administration - swallowing difficulties:

All patients who develop swallowing difficulties will be referred to Speech and Language therapists for an assessment. There is a licensed oral suspension of riluzole 5 mg in 1 ml available, however this formulation is expensive and costs approximately £2,400 per annum whereas tablets cost approximately £169 per annum.

The tablets can be used in an off label manner, i.e. crushed and mixed with soft food e.g. yoghurt or puree to aid swallowing. Tablets crushed onto food should be eaten within 15 minutes as there is no stability data available for this method of administration. Use crushed tablets with care as they may have a local anaesthetic effect in the mouth.

STH has up to 2 years' experience of crushing non-proprietary tablets without adverse events.

**Administration – enteral tubes:**

There is no experience / data to support use of the oral suspension via an enteral feeding tube. Feedback to date indicates suspension is viscous and so may be difficult to administer via a tube.

The tablets can be crushed and dispersed in water for enteral tube administration. Give immediately. Riluzole may block enteral feeding tubes, so ensure that the tube is flushed well after each dose.

**Duration of treatment**

Indefinite

**Contraindications**

Hepatic disease or baseline transaminases greater than 3 x the ULN.

Pregnancy, breast feeding.

Full list of side-effects / contraindications is given in the riluzole summary of product characteristics (SPC), available from [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk) .

**Side-effects**

The details below are not a complete list and the BNF and the SPC remain authoritative

Nausea, vomiting, weakness, tachycardia, somnolence, headache, dizziness, vertigo, pain, paraesthesia, neutropaenia and alterations in liver function tests. Transient increases in ALT can occur in the first 3 months of treatment, with levels returning to below twice the upper limit of normal after 2 to 6 months while treatment continues.

**Monitoring****Monitoring requirements****Secondary Care**

LFTs before and during therapy every month for the first 3 months. If within normal range patients will be transferred to primary care.

**Primary Care**

LFTs every 3 months for a further 9 months, and annually thereafter. GPs may be asked to take bloods in the first 3 months

ALT levels should be measured more frequently in patients who develop elevated ALT levels.

Riluzole should be discontinued if ALT levels increase to 5 x the upper limit of normal (ULN). There is limited experience with dose reduction or re-challenge in these patients.

Patients should be warned to report any febrile illness to their physicians. White blood cell counts should be checked and riluzole discontinued if :

WBC  $<3.5 \times 10^9/l$

Neutrophils  $<2 \times 10^9/l$

**Interactions**

The details below are not a complete list and the current BNF and the SPC remain authoritative.

No clinical data available but since riluzole is extensively metabolised by the enzyme cytochrome P450 1A2, inhibitors (e.g. theophylline, quinolones) and inducers (e.g. rifampicin, omeprazole) of this enzyme could potentially affect the rate of elimination.

### **Responsibilities of consultant clinician**

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent. This is particularly important for unlicensed products.
- To initiate riluzole in appropriate patients
- To monitor as above
- To prescribe the first 3 months supply or until patient stable
- To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care guideline
- To advise the GP regarding continuation of treatment, including the length of treatment
- To discuss any concerns with the GP regarding the patient's therapy
- The patient to remain under the consultants care whilst ever the patient is being prescribed riluzole

### **Responsibilities of the primary care clinician**

- To refer appropriate patients to secondary care for assessment
- To agree to prescribe for patients in line with the shared care agreement
- To report any adverse reaction to the CHM and the referring consultant
- To continue to prescribe for the patient as advised by the consultant
- To undertake monitoring as per shared care guideline above
- To inform the consultant if the patient discontinues treatment for any reason
- To seek the advice of the consultant if any concerns with the patient's therapy
- To conduct an annual **face to face** medication review or **more frequent if required**
- In the event that the GP is not able to prescribe, or where the SCG is agreed but the consultant is still prescribing certain items e.g. Hospital only product; the GP will provide the consultant with full details of existing therapy promptly by fax on request.
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems:  
[http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Practice%20resources%20and%20PGDs/Recording\\_SIDs\\_on\\_practice\\_clinical\\_systems.pdf](http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/Practice%20resources%20and%20PGDs/Recording_SIDs_on_practice_clinical_systems.pdf)

### **Responsibilities of patients/carers**

- Present rapidly to the GP or specialist should their clinical condition significantly worsen.
- Report any suspected adverse effects to their specialist or GP whilst taking riluzole.
- To read the drug information given to them
- To take riluzole as prescribed
- Inform the specialist, GP or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

## **Re-Referral guidelines**

Patients will remain under the care of neurology clinicians at STH and will be reviewed in outpatient clinics every 2-3 months but this will depend on health of individual patients.

## **Financial implications**

Commissioning of riluzole has been agreed and is included in the LCS-Services Over and Above Essential and Additional General Practice (not covered by a current LCS or DES).

## **Support, education and information**

Contact the consultant neurologist who is responsible for the patient as detailed in patient letters via RHH switchboard.

MND nurse, Theresa Walsh, is also available for advice on 0114 222 2266

## **Information for patients**

<http://www.mndassociation.org/Home>

## **References**

NEWT Guidelines for administration to patients with enteral feeding tubes or swallowing difficulties, May 2010

Handbook of Drug Administration via Enteral Feeding Tubes, third edition

<http://www.intranet.sheffieldccg.nhs.uk/Downloads/Medicines%20Management/prescribing%20guidelines/Dysphagia%20Guidelines%20on%20the%20administration%20of%20medication%20to%20patients%20with%20dysphagia.pdf>

Full list of side-effects is given in the riluzole summary of product characteristics (SPC), available from [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk) .

## **Useful links / Additional information (e.g ordering information)**

### **NICE**

<https://www.nice.org.uk/guidance/ta20>

<https://www.nice.org.uk/guidance/ng42>

**(Template riluzole letter to GP)**

Dear Doctor

**RE:** ..... **DOB:** ..... **NHS No.** .....

**Address:** .....

Your patient has being started on and completed 3 months treatment with riluzole without any significant problems.

This treatment can now be prescribed by GPs under the Traffic Light System under the “shared care” arrangements. This shared care guideline has been approved by the Sheffield Area Prescribing Group.

<http://www.intranet.sheffieldccg.nhs.uk/medicines-prescribing/shared-care-protocols.htm>

Riluzole is the treatment of choice in motor neurone disease; it is the only drug currently licensed for this condition and the only medication proven to be effective in clinical trials. Riluzole has been shown to slow the progression of motor neurone disease and improve life expectancy, on average between 2-3 months although in clinical practice benefits vary between individual patients. The use of riluzole for motor neurone disease is recommended by the National Institute for Health and Care Excellence (Technology appraisal 20). As part of shared care arrangements please can you monitor LFTs, adherence, response and side effects to therapy every 3 months for the following 9 months, and annually thereafter? Will you also please undertake to prescribe for your patient?

***Please acknowledge you are happy to take on shared care by completing and returning the slip below to above address or by faxing to .....***

Do not hesitate to contact us if you have any concerns.

Yours sincerely

**Clinician's Name**

**Clinician's Title**

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**IMPORTANT REMINDER**

*The prescribing doctor is responsible  
for monitoring the patient on the medication being prescribed*

.....please tear here, return to address or fax

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**RE:** ..... **DOB:** ..... **NHS:**.....

**Address:** .....

- I AGREE to take on shared care of this patient
- I DO NOT AGREE to take on shared care of this patient

Signed .....  
GP Practice.....  
Date.....