

**Riluzole (Rilutek®)**

**Effective Shared Care Agreement For patients with amyotrophic lateral sclerosis (ALS) - a form of Motor Neurone Disease (MND)**

**Section 1: Shared Care arrangements and responsibilities**

**Section 1.1 Agreement to transfer of prescribing of Riluzole to GP**

**Patient details**

Name:	_____
Address:	_____
Date of Birth:	_____
NHS number:	_____

**Contact details**

**Consultant:**

Address:

Email:

Contact number:

**GP**

Address:

Email:

Contact number:

**Patient**

Name:

Contact number:

**Agreement to shared care, to be signed by GP and Consultant before prescribing is transferred to GP**

**Consultant**

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**GP**

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Patient**

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

## Section 1.2: Shared Care responsibilities

This shared care agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP feels that undertaking the roles outlined in the shared care agreement is outside their area of expertise or have clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between specialist, GP and patient.

### **The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

#### **Responsibilities of the specialist initiating treatment**

- Discuss with the patient options for treatment and the suitability of Riluzole
- Discuss the potential benefits and side effects of treatment with the patient
- Undertake baseline tests: LFTS-serum transaminases, including ALT should be measured before initiation of treatment.
- Initiate Riluzole treatment.
- Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient. Consultant attaches copy of Shared Care Agreement (SCA) from the trust intranet to printed letter.
- Commence treatment with Riluzole and once patient is on a stable dose between visits, consider transfer of prescribing and monitoring to GP. .
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Ensure this has been discussed with patient, and that patient has signed SCA form
- Regular follow-up of patient (at least annually)
- Communicate promptly with the GP when treatment is changed
- Warn patient to report any febrile illness.
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card)

#### **Responsibilities of the General Practitioner**

- Reply to the request for shared care as soon as practicable, and if required discuss shared care arrangements with patient
- Prescribe at the dose recommended
- Continue blood tests at the following intervals:
  - Liver function tests - ALT should be measured every month during the first 3 months of treatment, every 3 months during the remainder of the first year, and periodically thereafter.
- Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment
- Adverse drug monitoring and interaction monitoring.

- Refer patient to the specialist if his or her condition deteriorates
- Stop treatment on the advice of the specialist
- Report adverse events to the specialist and MHRA (via Yellow Card)

### Responsibilities of the patient

- To take the prescribed medication regularly unless advised by GP or specialist
- To attend scheduled appointments with consultant and GP and for monitoring as detailed above
- Report any adverse effects especially febrile illness to the consultant or GP.
- Share any concerns in relation to treatment.
- Report to the consultant or GP if they do not have a clear understanding of the treatment

## Section 2: General Information on Riluzole

### Background

ALS is a progressive, fatal neurodegenerative disorder with a median survival of 37 to 49 months. It is characterised by progressive deterioration of muscle tissue (amyotrophy) and specific effects on lateral columns of the spinal cord, including fibre loss and fibrillary gliosis (lateral sclerosis). Glutamate toxicity has been implicated as a factor causing neuronal damage. Death is due to respiratory failure

### Licensed Indication

Riluzole is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).

### Dosage and administration

The recommended daily dose in adults or elderly is 100 mg (50 mg every 12 hours).

No significant increased benefit can be expected from higher daily doses.

### Contraindications

Hypersensitivity to the active substance or to any of the excipients.

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

Patients who are pregnant or breast-feeding.

In patients with impaired renal function, riluzole is not recommended for use in patients with impaired renal function, as studies at repeated doses have not been conducted in this population

### Side effects

Asthenia, nausea, vomiting, headache, abdominal pain, dizziness, tachycardia, somnolence, oral paraesthesias, neutropenia, elevations in liver function tests.

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### **Drug Interactions<sup>1</sup>**

There is no actual data to evaluate interactions with other drugs, however it is thought that CYP 1A2 is the principal isozyme involved in the initial oxidative metabolism of riluzole. Inhibitors of CYP 1A2 (e.g. caffeine, diclofenac, diazepam, TCAs, theophylline and quinolones) could potentially decrease the rate of riluzole elimination, while inducers of CYP 1A2 (e.g. cigarette smoke, rifampicin and omeprazole) could increase the rate of riluzole elimination.

### **Monitoring**

Because of the risk of hepatitis, serum transaminases, including ALT, should be measured before and during therapy with riluzole. ALT levels should be measured more frequently in patients who develop elevated ALT levels.

Patients should be warned to report any febrile illness to their physicians. The report of a febrile illness should prompt physicians to check white blood cell counts and to discontinue riluzole in case of neutropenia

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<sup>1</sup> BNF 66 September 2013-March 2014