

## Riluzole

Shared care guidelines for the management of patients prescribed riluzole in the management of Motor Neurone Disease

### AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of oral riluzole for the management of patients with Motor Neurone Disease is shared between the specialist and general practitioner (GP). It is intended to apply to patients who have been initiated on treatment by a neurological specialist experienced in the management of motor neurone disease (MND) **in accordance with the guidance published by the National Institute for Clinical Excellence** (Appraisal number 20, January 2001).

GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

**The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

### RESPONSIBILITIES and ROLES

Specialist responsibilities	
1	To assess the patient and establish the diagnosis of Motor Neurone disease of the amyotrophic lateral sclerosis type.
2	To assess the patient's suitability for treatment with riluzole. This should include checking for any contra-indications.
3	To arrange baseline/pretreatment blood count and liver function tests.
4	Initiate treatment and provide at least the first 2 months supply.
5	Discuss the benefits and side effects of treatment with the patient.
6	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.
7	Supply GP with summary within 14 days of a hospital out-patient review or in-patient stay.
8	Review the patient's condition and monitor response to treatment regularly where indicated.
9	Provide the GP with a copy of the monitoring undertaken and agree with the GP arrangements for ongoing monitoring.
10	Give advice to the GP on when to stop treatment.
11	Report adverse events to the Commission on Human Medicines (CHM)
12	Ensure that clear backup arrangements exist for GPs to obtain advice and support.

General Practitioner responsibilities	
1	Reply to the request for shared care as soon as practicable.
2	Prescribe medicine at the dose recommended.
3	Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs.
4	Liaise with the specialist if the patient develops any hepatic dysfunction or neutropenia whilst on therapy.
5	Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
6	Stop treatment on the advice of the specialist.
7	Report adverse events to the specialist and CHM.

*This Shared Care Guideline should be read in conjunction with the Summary of Product Characteristics (SPC) for riluzole tablets*

*Document prepared by Peter Davies Senior Pharmacist Salisbury district hospital with input from Dr B Ghosh and Dr J Lovett Consultant Neurologists*

# Salisbury NHS Foundation Trust Drugs and Therapeutics Committee

## Patient's role

- 1 Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
- 2 Share any concerns in relation to treatment with medicine.
- 3 Report any adverse effects to the specialist or GP whilst taking the medicine.

## BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Secretary for Dr B Ghosh Dr Joanna Lovett	01722 429233 Ex 4233			

## SUPPORTING INFORMATION

### Summary of condition and licensed indications.

The indication covered by this shared care guideline is for the management of patients with Motor Neurone Disease. The manufacturer's summary of product characteristics (SPC) should be referred to for full prescribing information.

### Treatment Aims (Therapeutic plan)

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

Clinical trials have demonstrated that riluzole slows progression of disease. There is no evidence that Riluzole improves motor function, lung function, fasciculations, muscle strength or motor symptoms.

It is not appropriate to use riluzole in patients with severe disability at diagnosis or in patients entering the terminal phase of their disease. Riluzole has not been shown to benefit patients with other forms of motor neurone disease such as primary lateral sclerosis.

### Treatment Schedule (including dosage and administration)

The dose of riluzole is 50mg twice daily

### Contra-indications

The summary of product characteristics includes the following contra-indications:

- hepatic disease or baseline transaminases greater than 3 times the upper limit of normal;
- patients who are pregnant or breast-feeding;
- severe hypersensitivity to riluzole or the excipients;

In addition to the above contra-indications, riluzole is not recommended for use in patients with renal impairment or for children.

### Precautions for use

Riluzole is associated with a small risk of abnormal liver function and neutropenia.

Riluzole should be prescribed with caution in patients with a history of abnormal liver function, or in patients with slightly raised liver function tests (LFTs). Baseline elevation of several LFTs should preclude the use of riluzole. (Refer also to contra-indications.)

Blood count and liver function tests should be monitored:

- before treatment;
- at monthly intervals for the first three months;
- then, three monthly for nine months;
- thereafter, annually.

LFTs should be monitored more frequently in patients who develop raised levels. Riluzole should be discontinued if liver enzymes rise to five times the normal level.

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Patients or their carers should be told how to recognize signs of neutropenia and be advised to seek immediate medical attention if symptoms such as fever occur. Neutropenia requires discontinuation of riluzole.

Patients should also be warned about the potential for dizziness or vertigo and advised not to drive or operate machinery if these symptoms occur.

## Side-effects

Most common adverse effects are asthenia, nausea and elevations in liver function tests.

Other adverse effects include headache, abdominal pain, vomiting, dizziness, tachycardia, somnolence and circumoral parasthesia.

Dizziness or vertigo may affect performance of skilled tasks (e.g driving)

Anaphylactoid reaction, angioedema and pancreatitis have been reported very rarely. Neutropenia has also been reported.

Interstitial lung disease. Perform chest radiography if symptoms such as dry cough or dyspnoea develop; discontinue if interstitial lung disease is diagnosed.

## Monitoring

Parameter	Frequency of monitoring	Action
Hepatic function	Before starting treatment At monthly intervals for the first 3 months Then 3 monthly for nine months Then annually thereafter	LFTs should be monitored more frequently in patients who develop raised levels. Riluzole should be discontinued if liver enzymes (ALT) rises to five times the normal level
Full Blood cell count with differential WBC	Before starting treatment At monthly intervals for the first 3 months Then 3 monthly for nine months Then annually thereafter (more often if liver function disturbance develop) Recheck FBC if patient presents with a febrile illness	Neutropenia requires discontinuation of riluzole
Chest radiography to check for interstitial lung disease	Only if symptoms such as dry cough or dyspnoea develop	Discontinue riluzole if interstitial lung disease is diagnosed

## Drug Interactions

No clinical data is available but since riluzole is extensively metabolized by the liver, there is a possibility of interactions with a number of drugs.

Drugs that may decrease elimination of riluzole include diclofenac, diazepam, some antidepressants and quinolones. Drugs that could increase elimination of riluzole include rifampicin and omeprazole.

The manufacturer's SPC should be consulted for full details.

## Cost

At Drug Tariff current prices (June 2016), one year's treatment with medicine at the dose of 50mg twice daily is £250

## References

1. eSPC for Riluzole December 2013
2. BNF 71, September- March 2016
3. NICE TAG20; Guidance on the use of riluzole for the treatment of motor neurone disease, January 2001

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