**Oxford Radcliffe Hospitals NHS Trust, Oxfordshire Primary Care Trust, Nuffield Orthopaedic Centre and Oxfordshire Mental Health NHS Trust Shared Care Protocol and Information for GPs**

# Riluzole

**This leaflet provides the necessary information and guidance for the shared care of adult patients requiring Riluzole therapy**


**Summary**

**Background**
Riluzole is licensed for the treatment of the Amyotrophic Lateral Sclerosis (ALS) form of Motor Neurone Disease (MND), which accounts for 85% of cases of MND. Cochrane meta-analysis of clinical trials has shown around a 10% increase in tracheostomy free survival at one year. It is unknown if treatment for longer periods leads to further prolongation of survival, but there is anecdotal evidence that this is possible. Importantly, the slowing of disease progression may occur early on and therefore it is hoped that the drug is preventing progression to a state of disability rather than prolonging the severe disability stage. NICE have recommended this drug be available and Oxfordshire Health Authority have issued a revised Lavender Statement implementing the NICE guidelines. It is estimated that 8-10 patients per year in Oxfordshire may be appropriate for Riluzole, and that patients will on average be on the drug for 2 years.

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

**Prescribing Information**
The drug is prescribed by the General Practitioner on the recommendation of a neurologist. The dose is 50mg two times per day. 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 the extremely rare case of neutropenia.

The average patient with ALS/MND would be expected to survive for 18-24 months from diagnosis but there is a wide variation as some patients present late and 10% of patients survive more than ten years (range 10-20 years). It is generally agreed by Neurologists treating MND that it is not clinically appropriate to treat patients in the terminal phase of the illness or those with extremely slow progression. However, defining a 'terminal' phase in which to withdraw Riluzole from patients already taking it is likely to be based on individual considerations. Given the high cost of the drug it is important that it is focused on patients who are most likely to benefit. It is suggested that the issue of when the drug should be stopped is openly discussed with the patient at the time of first prescription and that subsequently there is close liaison between Neurologists, GPs and Palliative Care Specialists.

**Adverse effects**
The drug is generally well tolerated. The commonest side effects are mild nausea and fatigue which lead to 10-15% of patients stopping treatment in clinical trials. There is an idiosyncratic rise in liver enzymes which lead to the drug being stopped in 1-2% of patients in clinical trials. An initial rise of liver transaminases (ALT) should prompt re-testing after 2 weeks. Elevations of 2-3 fold which then plateau do not always necessitate stopping the drug, and dose reduction to 50mg once daily can be considered.

Other common side effects of the drug found in clinical trials (occurring in between 1-10% of patients) were headache, dizziness, diarrhoea and tachycardia.

Cases of interstitial lung disease and neutropenia have also been reported in patients treated with riluzole. However these are very uncommon.

**Contra-indications/Cautions**
Riluzole should be prescribed with care in patients with a history of abnormal liver function**.** Baseline elevations of liver enzymes (especially elevated ALT) should preclude the use of riluzole. Also if ALT rises to five times the normal value then riluzole should be discontinued and not restarted.

Riluzole is not recommended for use in patients with impaired renal function.

**Pregnancy and lactation**
Riluzole is contraindicated in women who are pregnant or breast-feeding.

**Drug interactions (refer also to BNF or SPC)**
There are no known significant drug interactions with riluzole.

**Monitoring**
Baseline bloods (Liver function tests and Full Blood Count) should be taken before starting treatment and at monthly intervals for the first 3 months and then every 3 months for the first year of treatment, and annually thereafter.

**Patient information leaflet**
Patients should be supplied with the MNDA information leaflet at their clinic visit.

**Shared Care Responsibilities**
Shared care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them. Patients should be under regular follow-up which provides an opportunity to discuss drug therapy.

a) Aspects of care for which the Hospital Consultant is responsible:
- Take baseline bloods and establish that there are no contra-indications to starting treatment with riluzole.
- Write to the GP requesting shared care and outline shared care protocol criteria.
- Liaise with GP regarding changes in disease management, drug dose, and missed clinic appointments.
- Ensure clinical supervision of the patient is done by follow-up as appropriate.
- Ensure the patient understands the nature and complications of drug therapy and their role in reporting adverse effects promptly.
- Provide clear instruction to GP on when therapy needs to be referred back to specialist.
- Be available to give advice to GP and patient.
- Supply the patient with a MNDA information leaflet.

b) Aspects of care for which the GP is responsible:

- Prescribe riluzole according to the information in this protocol.
- Monitor LFTs (ALT and bilirubin) and FBC with differential WCC. This should done at monthly intervals from start of treatment for 3 months, then 3 monthly until 12 months after start of treatment, and then annually thereafter. Monitor ALT more frequently if it is raised.
- Monitor for adverse effects as detailed above.
- Advise the Hospital Consultant of any clinical changes or adverse effects where appropriate.
- Contact the consultant in writing to request them to take blood from the patient at their next clinic visit if this has not been possible at the GP surgery.
- Inform the hospital consultant if ALT level is more than 3 times the normal upper limit.
- Stop riluzole and inform hospital consultant if ALT level is more than 5 times the normal upper limit

c) Aspects of care for which the Patient is responsible:

- Report any adverse effects, including any febrile illness (high temperature) to their GP and/or consultant
- Attend for regular monitoring as outlined in patient information leaflet.

**Contact Details**

In case of an emergency or general query please use the contacts below;

Medical Team
Secretary to Professor Talbot/Dr Turner (9-5 only)
☎01865 231893

On call neurology Specialist Trainee or Professor Talbot/Dr Turner for emergencies via John Radcliffe Hospital switchboard

Pharmacy
Neurosciences pharmacist: ☎01865 231628/ 572728 or bleep 4655/6242 via John Radcliffe Hospital switchboard

On-call pharmacist (out of hours) Bleep 1884 via John Radcliffe Hospital switchboard

John Radcliffe Hospital switchboard
☎01865 741166