Riluzole

ESCA: For the treatment 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 riluzole for motor neurone disease can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel confident to undertake this role, then you are 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.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with motor neurone disease are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

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. Confirm the diagnosis of motor neurone disease
2. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient
3. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
4. Do baseline monitoring - LFTS-serum transaminases, including ALT - prior to initiation of riluzole
5. Initiate treatment and stabilise dose of riluzole
6. Review the patient's condition and monitor response to treatment at 3 months after initiation of treatment and to carry out 3 month liver function tests and full blood count at this visit. The patient should have blood pressure measurement and recording of adverse events.
7. Ask GP to arrange 3 month liver function tests and white blood cell measurement.
8. Review the need for continuing treatment after 18 months of therapy (this being the period of time over which riluzole was shown to be beneficial in the clinical trials).
9. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
10. Report serious adverse events to the MHRA
11. Ensure clear backup arrangements exist for GPs, for advice and support (Please complete details below)

General Practitioner responsibilities						
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days						
2. Prescribe riluzole at the dose recommended						
3. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement						
GP Prescribing System	**Read Code**	**Description**		**GP Prescribing System**	**Read Code**	**Description**
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care
4. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist						
5. Continue blood tests at the following intervals (As per MTRAC) 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.						
6. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment						
7. Refer back to specialist if condition deteriorates						
8. Report serious adverse events to specialist and MHRA						
9. Stop treatment on advice of specialist						

Patient's role
1. Report to the specialist, clinical nurse 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 riluzole with the specialist, clinical nurse specialist or GP
3. Report any adverse effects especially febrile illness to the consultant or GP whilst taking riluzole
4. Report any adverse effects to the specialist or GP whilst taking riluzole
5. Attend regular outpatient appointments with the specialist

BACK-UP ADVICE AND SUPPORT

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Based on MTRAC template
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SUPPORTING INFORMATION

Indication	Riluzole is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).	
Dosage and Administration	Treatment should only be initiated by specialist physicians with experience in the management of motor neurone diseases. The recommended daily dose in adults or older people is 100 mg (50 mg every 12 hours)	
Renal Impairment	Riluzole is not recommended for use in patients with impaired renal function	
Hepatic impairment	Riluzole should be prescribed with care in patients with a history of abnormal liver function, or in patients with slightly elevated serum transaminases	
Contra-indications / Special precautions	**Contraindications** Hypersensitivity to the active substance or to any of the excipients listed Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal. Patients who are pregnant or breast-feeding. **Cautions** <u>Liver impairment</u> Riluzole should be prescribed with care in patients with a history of abnormal liver function, or in patients with slightly elevated serum transaminases (ALT/SGPT; AST/SGOT up to 3 times the upper limit of the normal range (ULN)), bilirubin and/or gamma-glutamyl transferase (GGT) levels. Baseline elevations of several liver function tests (especially elevated bilirubin) should preclude the use of riluzole. Because of the risk of hepatitis, serum transaminases, including ALT, should be measured before and during therapy with riluzole. 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. ALT levels should be measured more frequently in patients who develop elevated ALT levels. Riluzole should be discontinued if the ALT levels increase to 5 times the ULN. There is no experience with dose reduction or rechallenge in patients who have developed an increase of ALT to 5 times ULN. Readministration of riluzole to patients in this situation cannot be recommended. <u>Neutropenia</u> 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. <u>Interstitial lung disease</u> Cases of interstitial lung disease have been reported in patients treated with riluzole, some of them were severe. If respiratory symptoms develop such as dry cough and/or dyspnoea, chest radiography should be performed, and in case of findings suggestive of interstitial lung disease (e.g. bilateral diffuse lung opacities), riluzole should be discontinued immediately. In the majority of the reported cases, symptoms resolved after medicinal product discontinuation and symptomatic treatment. <u>Renal impairment</u> Studies at repeated doses have not been conducted in patients with impaired renal function	
Side Effects	**Very common**	Nausea, abnormal liver function tests, asthenia
	Common	Headache, dizziness, oral paraesthesia, somnolence, tachycardia, diarrhoea, abdominal pain, vomiting, pain
Monitoring	Serum transaminases, including ALT, should be measured before and during therapy with riluzole. 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. ALT levels should be measured more frequently in patients who develop elevated ALT levels. Riluzole should be discontinued if the ALT levels increase to 5 times the ULN. Re-administration of riluzole to patients in this situation cannot be recommended. Patients should report febrile illness to their physicians. White blood cell count should be checked in these circumstances.	

Drug Interactions	There have been no clinical studies to evaluate the interactions of riluzole with other medicinal products. In vitro studies using human liver microsomal preparations suggest that CYP 1A2 is the principal isozyme involved in the initial oxidative metabolism of riluzole. Inhibitors of CYP 1A2 (e.g. caffeine, diclofenac, diazepam, nicergoline, clomipramine, imipramine, fluvoxamine, phenacetin, theophylline, amitriptyline and quinolones) could potentially decrease the rate of riluzole elimination, while inducers of CYP 1A2 (e.g. cigarette smoke, charcoal-broiled food, rifampicin and omeprazole) could increase the rate of riluzole elimination

References

Rilutek SmPC
Rilutek BNF
MTRAC verdict
NICE TA20: Guidance on the Use of Riluzole (Rilutek) for the Treatment of Motor Neurone Disease

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I agree to participate in this shared care agreement for the treatment of the below named patient with riluzole for motor neurone disease.

General Practitioner
Name (please print)_____Signature _____Date_____

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant at: