

Riluzole Shared Care Guideline

Introduction

General Statements	<p>The following guidelines are designed to provide information relating to riluzole and to outline the responsibilities of the primary and secondary care teams in its prescribing for the treatment of the Amyotrophic Lateral Sclerosis form of motor neurone disease. It should be read in conjunction with the Summary of Product Characteristics</p> <p>Riluzole therapy should be initiated by a neurological specialist with expertise in the management of MND. Routine supervision of therapy should be managed by locally agreed shared care protocols.</p> <ul style="list-style-type: none"> The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between the Consultant and GP The GP must reply in writing to the request for shared care as soon as practicable, before the shared care commences, to confirm if unwilling to participate. That the responsibility for prescribing and monitoring must be clearly documented in the patient's hospital and GP notes That the agreement to consider the use of a shared care guideline is only considered when the patient's clinical condition is stable or predictable
Indication	<p>NICE guidance, number 20, issued in January 2001 recommends the use of riluzole for the treatment of the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND).</p> <p>Riluzole is licensed to extend life or the time to mechanical ventilation for patients with ALS.</p> <p>Riluzole is not licensed for other forms of Motor Neurone disease.</p>

Individuals Responsibilities

Hospital Specialist's Responsibilities	<ol style="list-style-type: none"> 1. Confirm diagnosis of the ALS form of MND and indication for drug in patient. 2. To assess liver function test, renal function and full blood count before starting treatment and then at week 1, week 2, month 1, month 2, month 3. Ask about febrile illness at each visit. 3. To initiate treatment. Patients will receive 3 months treatment from secondary care. 4. To send a letter to the GP requesting Shared care for a particular patient. This letter will contain the following information <ul style="list-style-type: none"> ○ Diagnosis ○ Results of blood tests ○ Results of any other appropriate investigations ○ Dose and name of treatment ○ Advice on dose alterations where appropriate 5. To periodically review the patient.
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	<p>6. Evaluation of adverse effects / monitoring results reported by the GP.</p> <p>7. Deciding when it is appropriate to withdraw therapy.</p>
General Practitioner's Responsibilities	<ol style="list-style-type: none"> 1. To contact the referring consultant without delay if they are not willing to enter into a Shared Care agreement 2. To monitor the patient's overall health and well being 3. To carry out appropriate three-monthly monitoring (see below) 4. To prescribe treatment 5. To monitor side effects of treatment, and seek urgent advice as necessary 6. To contact the appropriate secondary care physician as appropriate 7. Be aware of iatrogenic neutropenia and consider using electronic reminder systems if available.
Monitoring Required	<p>Monitoring in primary care</p> <p>Liver Function Test Every three months (after the first 3 months monitoring, which is undertaken by the Hospital Specialist).</p> <p>Monitor more frequently in the event of elevated ALT or other LFTs (see below).</p> <p>Full Blood Count To be done when patient experiences signs of febrile illness</p> <p>Ask about the presence of rash / oral ulceration at each visit</p>
When and How to Discontinue Treatment	<p>Please note- up to 10-15% of patients develop transient elevation of ALT, AST > 3x upper limit of normal, returning to normality after 3 months</p> <ul style="list-style-type: none"> • If ALT or other LFTs are elevated but less than 3x upper limit of normal, repeat LFTs. If still elevated after repeat test, continue treatment and contact Hospital Specialist for advice. • If ALT or other LFTs are elevated greater than 3x upper limit of normal but less than 5x upper limit of normal, continue treatment and contact Hospital Specialist for advice. • If ALT or other LFTs are elevated greater than 5x upper limit of normal, or if the patient develops symptoms of liver failure, discontinue treatment immediately and contact Hospital Specialist for urgent advice. <p>White blood cells should be determined in febrile illness. Discontinue treatment and refer to specialist if neutropenic</p>
Information given to the patient	<p>Patients and their carers should be told how to recognise signs of neutropenia or liver failure, and advised to seek immediate medical attention if symptoms such as fever occur.</p> <p>Warn patient -Dizziness or vertigo may affect performance of skilled tasks, e.g. Driving</p>
Contact Details	See relevant Consultant letter

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Product Information	
The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and Summary of Product Characteristics	
Dosage	50mg every 12 hours
Adverse Effects	<p>The following side effects occurred at a frequency of 1% or more among ALS patients receiving riluzole 100mg OD and were greater than placebo by 1%, or were serious side effects with frequency greater than placebo. nausea, vomiting, headache, asthenia, tachycardia, abdominal pain, somnolence, dizziness, vertigo, alterations in liver function tests</p> <p>Refer to the BNF online and www.medicines.org.uk/emc/ for complete and up to date information.</p>
Precautions and Contra-indications	<p>Contra-indications</p> <ul style="list-style-type: none"> • Severe hypersensitivity to riluzole or any of the excipients. • Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal (ULN) • Patients who are pregnant or breastfeeding • Children - the safety and effectiveness of riluzole in children has not been studied • Impaired renal function - studies at repeated doses have not been conducted in this population <p>Use with caution in Liver impairment Neutropenia - patients should be advised to report any febrile illness to their doctor. Treatment should be discontinued in the case of neutropenia</p> <p>Refer to the BNF online and www.medicines.org.uk/emc/ for complete and up to date information.</p>
Clinically relevant Drug Interactions and their management	Refer to the BNF online and www.medicines.org.uk/emc/ for complete and up to date information.