Royal United Hospitals Bath
NHS Foundation Trust

Riluzole

For the management of motor neurone disease (MND), specifically amyotrophic lateral sclerosis (ALS)

Shared Care Protocol

Background: Riluzole is recommended for the management of individuals with the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND).[1]

Introduction: At present, Riluzole is the only licensed drug treatment for patients with ALS and is indicated to extend life or time to mechanical ventilation.

There is no evidence that Riluzole exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength and motor symptoms. Riluzole has not been shown to be effective in the late stages of ALS.

Safety and efficacy of Riluzole has only been studied in ALS. Therefore, Riluzole should not be used in patients with any other form of motor neurone disease.[2]

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 undertaken by general practitioners (GPs).

Shared Care Responsibilities

Specialist Responsibility	
1.	To ensure suitability of patient before start of treatment
2.	Write to GP requesting shared care and outline the details
3.	Provide GP with appropriate prescribing information and any additional information requested.
4.	Agree with GP arrangements for ongoing monitoring to ensure safe use of Riluzole.
5.	Ensure the patient is aware of what to do and who to contact if they experience adverse effects.
6.	To be available to give advice to both patient and GP
7.	To inform GP when it is considered appropriate to discontinue treatment
General Practitioner Responsibility	
1.	Agreement to shared care guideline by the consultant
2.	Carry out baseline / pre-treatment blood count and liver function tests
3.	Prescribe the drug treatment as described
4.	Request advice from the specialists as necessary
5.	Report any adverse effects to the specialist and stop treatment if an urgent need arises.

6.	Monitor blood results (FBC, creatinine and electrolytes and LFTs) every 3 months up to one year, then ensure FBC and LFTs are repeated annually.
7.	Monitor and deal with any general health issues of the patient.
Patient or parent/carer	
1.	Attend all appropriate consultant and GP appointments
2.	Read any written information on the medication e.g. Patient information leaflet
3.	Report to the specialist or GP if patient does not have a clear understanding of the treatment.
4.	Share any concerns in relation to treatment with Riluzole
5.	Seek help urgently if any febrile illness or respiratory symptoms occur and advise GP or consultant of this

Dose and Administration

The recommended daily dose in adults is 100 mg (50 mg twice a day).

Method of administration:

Oral use

The liquid form of Riluzole (Teglutik) is reserved for patients who have bulbar symptoms and risk of dysphagia or who have a gastrotomy. Riluzole is available in liquid form (Teglutik) 5mg/ml with a usual dose of 10ml twice a day. [3]

Contraindications

Riluzole is contra-indicated in patients with:

- Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal.
- Patients who are pregnant or breast-feeding
- Impaired renal function
- Severe hypersensitivity to Riluzole or the excipients

Special warnings and precautions for use:

Liver impairment:

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.

Neutropenia:

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

Interstitial lung disease:

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.

Effects on ability to drive and use machines:
Patients should be warned about the potential for dizziness or vertigo, and advised not to drive or operate machinery if these symptoms occur.

References

1. **Guidance on the use of Riluzole (Rilutek) for the treatment of Motor Neurone Disease.** *Last updated 23 July 2019*
https://www.nice.org.uk/guidance/ta20/chapter/1-Guidance (Accessed 1 July 2020)

2. **Therapeutic indications of Riluzole (Rilutek)** *Last updated 17 June 2019*
https://www.medicines.org.uk/emc/product/1101 (Accessed 1 July 2020)

3. **Teglutik 5mg / ml oral suspension** *Last updated 28 February 2020*
https://www.medicines.org.uk/emc/product/5060 (Accessed 1 July 2020)

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