Information Regarding the Prescription of Riluzole

Riluzole (Rilutek)

for patients with Amyotrophic Lateral Sclerosis

Background
Riluzole is reported to prolong life, or time to mechanical ventilation in Amyotrophic Lateral Sclerosis (ALS), the main form of Motor Neurone Disease. It is envisaged that patients selected for treatment will receive riluzole continuously, on average one or two years from diagnosis. ALS is a neurodegenerative disorder characterized by progressive loss of upper and lower motor neurones. Riluzole is neuroprotective. It acts by inhibiting pre-synaptic release of glutamate, an excitatory neurotransmitter in the CNS which is cytotoxic when overexpressed at nerve terminals. Although the aetiology of ALS is unclear, neuropathology is related to impaired transport and subsequent accumulation of glutamate in the corticospinal tract and motor cells of the brain and lower motor neurones.

The National Institute of Clinical Excellence has recommended Riluzole for use in patients with Motor Neurone Disease.

This leaflet provides information on Riluzole treatment guidelines of therapy between the hospital and GP concerned.

Indications for Therapy
Patients considered for riluzole therapy will satisfy the following criteria:

1 . Diagnosis of ALS type Motor Neurone Disease
2. Disease onset < 5 years
3. Adequate renal function (creatinine < 200micromols/l)
4. Liver function with no major elevation of serum transaminases i.e. ALT<90 unit/l (13-43u/1)
5. Full Blood Count (FBC) within normal limits

Dosage and Administration

One tablet (50mg) twice daily, there is no indication for increasing this dose.

Availability
Community pharmacists may obtain this drug through local wholesalers

Hospital Responsibility
Diagnosis of ALS
Recommendation of treatment by Consultant Neurologist.

GP Responsibility
Prescription of riluzole
Initial Monitoring
FBC - monthly for first three months
LFT's - monthly for first three months
Creatinine - monthly for first three months
Adverse Effects
Monitoring of bloods after 3 months: Every three months - FBC, LFT's, Creatinine
Refer for specialist opinion in event of an abnormal result.
Adverse effects - Any adverse effect should be reported to C.S.M.

Discontinuation of therapy
(Discontinue therapy and refer immediately to neurologists)
Agranulocytosis
LFT's more than double normal limits (>90u/l)
Creatinine >200 micromol/l

Side effects
Asthenia has been commonly reported but symptoms of energy lack, loss of strength and weakness are also characteristic of MND. Gastrointestinal upsets including abdominal pain or discomfort and nausea and vomiting are relatively common. Other reported side effects include dizziness, tachycardia, somnolence and facial (circumoral) paraesthesia. The potential for altered liver function is well established, hence the need for regular monitoring.

Drug Interactions
Interactions have not been established in the clinical trials to date. However, riluzole is extensively metabolised by the liver cytochrome P450 system and the potential for interaction with liver enzyme inhibitors and/or inducers should be recognised. Concurrent therapy with drugs which are metabolised by the same liver enzyme group (e.g. amitriptyline, ciprofloxacin, diazepam etc.) might result in reduced elimination and manifest as toxicity. Alternatively, there is speculation that rifampicin, omeprazole or lansoprazole may induce hepatic metabolism of riluzole so reducing dose-related activity.

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