

Southern Derbyshire Health Shared Care Guidelines

RILUZOLE for the treatment of the amyotrophic lateral sclerosis (ALS) form of Motor Neurone Disease (MND).

Clinical details

Riluzole is licensed to extend life or the time to mechanical ventilation for individuals with the amyotrophic lateral sclerosis (ALS) form of motor neurone disease (MND).

The incidence of ALS ranges from 1.8 to 2.2 per 100,000 population and prevalence ranges from 4.0 to 4.7 per 100,000 population in the UK.

Motor Neurone Disease is the term used to describe progressive muscular atrophy (PMA) and amyotrophic lateral sclerosis (ALS) which includes Progressive Bulbar Palsy.

ALS, which is characterised by both upper and lower motor neurone signs, is the most common form of MND, accounting for 65% to 85% of all cases. Adult-onset MND is characterised by progressive degeneration of the motor neurones of the brain, brain stem or spinal cord, starting insidiously with symptoms and signs including stumbling, foot drop, weakened grip, slurred speech, cramp, muscle wasting, twitching and tiredness. Other symptoms of MND include muscle stiffness, paralysis, incoordination, and impaired speech, swallowing and breathing. Most individuals die from ventilatory failure, resulting from progressive weakness and wasting of limb, respiratory and bulbar muscles within approximately 3 years of the onset of symptoms.

Diagnosis of ALS requires the demonstration of clinical signs affecting both the brain and spinal cord.

Product and dosage details

Product: Riluzole 50mg tablets.

Dose: 50mg every 12 hours

No significant increased benefit can be expected from higher daily doses.

Contraindications

Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal (ULN).

Renal impairment, pregnancy, breast-feeding.

Special precautions

Riluzole should be prescribed with care in patients with a history of abnormal liver function, or in patients with slightly elevated serum transaminases (ALT/AST up to 3 times the ULN), bilirubin and/or GGT levels. Baseline elevations of several LFTs (especially elevated bilirubin) should preclude the use of riluzole.

Monitoring

Liver function tests before and during therapy, every month for 3 months, then every 3 months for a further 9 months, and annually thereafter. ALT levels should be measured more frequently in patients who develop elevated ALT levels.

Riluzole should be discontinued if ALT levels increase to five times the ULN. There is limited experience with dose reduction or rechallenge in these patients.

Patients should be warned to report any febrile illness to their physicians. White blood cell counts should be checked and riluzole discontinued in case of neutropenia.

Side-effects

Nausea, vomiting, weakness, tachycardia, somnolence, headache, dizziness, vertigo, pain, parasthesia and alterations in liver function tests.

Drug interactions

No clinical data available but since riluzole is extensively metabolised by the enzyme cytochrome P450 1A2, inhibitors(e.g theophylline, quinolones) and inducers (e.g. rifampicin, omeprazole) of this enzyme could potentially affect the rate of elimination.

Consult product literature for more details.

Aspects of care for which the specialist physician with experience in the management of MND is responsible

Diagnosis of ALS after appropriate investigations.

Initiation of riluzole and prescribing for the first 3 months of therapy.

Monitoring the progress of the disease.

Monitoring the patient with regard to side-effects and liver function tests in the first 3 months of treatment.

Assessment of the continuing need for treatment.

Conditions of assuming responsibility by the GP

Prescribing responsibility will only be transferred to the GP after the first 3 months of therapy.

Aspects of care for which the GP is responsible

Prescribing riluzole after the first 3 months of therapy

Monitoring the patient with regard to side-effects and liver function tests.

Referral back to the specialist physician if side-effects become troublesome, or in the presence of raised LFTs(see Monitoring section)

Individual consideration of each case between the Specialist physician and GP

On each occasion the consultant will discuss shared care with the GP before prescribing responsibility is transferred.

Patient Information leaflets

The manufacturers patient information leaflet will be provided with all riluzole dispensed.

For newly diagnosed patients, a booklet from the Motor Neurone Disease Association on practical management of the disease will be sent to the GP.

Back up care available to GP from secondary care

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