Riluzole

Oral Suspension

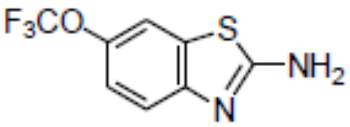
Product Name
Generic name: Riluzole Oral Suspension

Ingredient

The main ingredient is riluzole.

Chemical name：2-amino-6(trifluoromethoxy)benzothiazole

Chemical structural formula：



Chemical formula：$C_8H_5F_3N_2OS$
Molecular weight：234.20
pH value：7.5～9.5
The formulation of this drug does not contain bacteriostat.

Description
Slightly brown, opaque homogeneous suspension after being manually shaken.

Indication
This drug is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS).
Clinical trials have demonstrated that riluzole extends survival for patients with ALS. Survival was defined as patients who were alive, not intubated for mechanical ventilation and tracheotomy-free.
There is no evidence that this drug exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength and motor symptoms. This drug has not been shown to be effective in the late stages of ALS. Safety and efficacy of this drug has only been studied in ALS. Therefore, this drug should not be used in patients with any other form of motor neurone disease.

Strength
300ml : 1.5g

Dosage and administration
Treatment with this drug should only be initiated by specialist physicians with experience in the management of motor neurone diseases.

Posology
Adults and elderly people:
The recommended daily dose in adults or older people is 100mg (50mg every 12 hours). No significant increased benefit can be expected from higher daily doses. It is recommended to take 10ml two times a day of the suspension (i.e. 10ml corresponds to 50mg of riluzole). If you miss one dose, take the next dose as planned. Based on pharmacokinetic data, there are no special instructions for the use of this drug in this population.

Paediatric population:
It is not recommended for use in paediatric population, due to a lack of data on the safety and efficacy of riluzole in any neurodegenerative diseases occurring in children or adolescents.

Patients with impaired renal function:
It is not recommended for use in patients with impaired renal function, as studies at repeated doses have not been conducted in this population. (see Precautions)
Patients with impaired hepatic function:
see Contraindications, Precautions and Pharmacokinetic.

Method of administration
The suspension can be administered orally after shaken well. Dilution with liquids is not necessary. The suspension is administered by means of graduated dosing syringe.
Take at least 1 hour before or 2 hours after a meal. Measure serum aminotransferases before and during treatment.