**Teglutik® (riluzole) 5mg/ml Oral Suspension Prescribing Information**

**See Summary of Product Characteristics (SPC) before prescribing.**

**Presentation:** Oral suspension containing 5 mg of riluzole per 1 ml. **Indications:** To extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS). Survival in clinical trials was defined as being alive, not intubated for mechanical ventilation and tracheotomy-free. No evidence of efficacy in the late stages of ALS and should not be used for any other form of motor neurone disease (MND). **Dosage and administration:** For initiation by specialist physicians experienced in MND. Shake gently for at least 30 seconds by rotating the bottle by 180o and the homogeneity should be visually verified before measuring the dose using the oral syringe provided.

Dilution with liquids is not necessary. The suspension is suitable for oral administration and alternatively, it is also suitable for administration via enteral feeding tubes. The compatibility has been tested with tubes of silicone or polyurethane with diameters from 14Fr to 20 Fr. *Adults or elderly:* 10ml oral suspension (i.e. 50mg riluzole) twice daily (i.e. every 12 hours). *Paediatric population*: Not recommended due to lack of data. *Renal impairment:* Not recommended due to lack of data. *Hepatic impairment:* see below.**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Hepatic disease or baseline transaminases greater than 3 times the upper limit of normal. Patients who are pregnant or breast-feeding. **Warnings and precautions:** *Liver impairment:* Prescribe 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 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 (alanine aminotransferase), 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. Discontinue if ALT levels increase to 5 times the ULN. Re-administration of riluzole cannot be recommended. *Neutropenia:* Counsel patients to report any febrile illness and if reported, check white blood cell counts and discontinue in case of neutropenia. *Interstitial lung disease (ILD)*: Cases (some severe) have been reported. Perform chest radiography if patients develop respiratory symptoms such as dry cough and/or dyspnoea and in case of findings suggestive of ILD, discontinue riluzole immediately. In the majority of the reported cases, symptoms resolved after drug discontinuation and symptomatic treatment. *Renal impairment:* See above. *Other:* Patients with rare hereditary problems of fructose intolerance should not take this medicine because it contains liquid sorbitol (E420). **Interactions:** There have been no clinical studies to evaluate the interactions of riluzole with other medicinal products. *In vitro* studies suggest that CYP 1A2 is the principal isozyme involved in the initial oxidative metabolism of riluzole. Inhibitors of CYP 1A2 (e.g. caffeine, diclofenac, diazepam, nicergoline, clomipramine, imipramine, fluvoxamine, phenacetin, theophylline, amitriptyline and quinolones) could potentially decrease the rate of riluzole elimination, while inducers of CYP 1A2 (e.g. cigarette smoke, charcoal-broiled food, rifampicin and omeprazole) could increase the rate of riluzole elimination. **Pregnancy and Lactation:**  Contraindicated. **Fertility:** slightly impaired reproductive performance and fertility observed in rats at doses higher than the therapeutic dose. **Effects on ability to drive and use machines**: Advise patients not to drive or operate machinery if symptoms of dizziness or vertigo occur. No studies performed in this area. **Undesirable effects:** Adverse effects reported in phase III clinical studies conducted in ALS patients: *Very* *common (>1/10)*: nausea, abnormal liver function tests, asthenia. *Common (> 1/100 to < 1/10)*: headache, dizziness, oral paraesthesia, somnolence, tachycardia, diarrhoea, abdominal pain, vomiting, pain. *Uncommon (> 1/1000 to <1/100)*: anaemia, anaphylactoid reaction, angioedema, interstitial lung disease, pancreatitis. *Not known*: severe neutropenia, hepatitis. *Further information on hepato-biliary disorders*: Increased ALT usually appeared within 3 months after the start of therapy and were usually transient. These levels returned to below twice the ULN after 2 to 6 months while treatment was continued. These increases could be associated with jaundice. In patients (n=20) from clinical studies with increases in ALT to more than 5 times the ULN, treatment was discontinued and the levels returned to less than 2 times the ULN within 2 to 4 months in most cases. Study data indicate that Asians may be more susceptible to liver function test abnormalities compared with Caucasians. Also note that compared with riluzole tablets, the Cmax of riluzole oral suspension was approximately 20% higher. A slightly higher risk of the adverse events considered related to either dose or exposure of riluzole (e.g. dizziness, diarrhoea, asthenia and ALT increase) cannot be excluded. See SPC for further information on side effects. **Overdose:** Treatment is symptomatic and supportive. **Marketing authorisation number and Basic NHS Price:** PL 20663/0002. One bottle of 300ml Teglutik 5mg/ml Oral Suspension £100.00. **Marketing Authorisation Holder:** Italfarmaco S.A, C/ San Rafael, 3, Alcobendas, Madrid 28108, Spain. **Legal Category:** POM. **Further information:** Martindale Pharma, Bampton Road, Romford, RM3 8UG. Tel: 01277 266 600. **Date of Preparation:** March 2020.

Adverse events should be reported. Reporting forms and information can be found at

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Martindale Pharma, an Ethypharm Group Company. Tel: 01277 266 600. e-mail: [drugsafety.uk@ethypharm.com](mailto:drugsafety.uk@ethypharm.com)