TEGLUTIK® (riluzole) 5mg/ml Oral Suspension
Prescribing Information
Please refer to the Summary of Product Characteristics (SPC) before prescribing.
Presentation: Slightly brown, opaque homogeneous suspension after being manually shaken, containing 5 mg of riluzole per 1 ml of suspension. **Indications:** Teglutik® is indicated to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS). Teglutik® has not been shown to be effective in the late stages of ALS. Safety and efficacy of Teglutik® has only been studied in ALS, therefore Teglutik® should not be used in patients with any other form of motor neurone disease (MND). Please refer to the SPC for further information. **Dosage and administration:** The suspension can be given per oral administration. Dilution with liquids is not necessary. The suspension is administered by means of graduated dosing syringe. Treatment with Teglutik® should only be initiated by specialist physicians with experience in the management of MND. The recommended daily dose in adults or elderly is 100 mg (50 mg or 10 ml every 12 hours). No significant increased benefit can be expected from higher daily doses. *Children:* Not recommended for use in children, due to a lack of data. *Patients with impaired renal function:* Not recommended, as studies at repeated doses have not been conducted in this population. *Elderly:* based on pharmacokinetic data, there are no special instructions for the use of Teglutik® in this population. *Patients with impaired hepatic function:* Contraindicated in patients with hepatic disease or baseline transaminases greater than 3 times the upper limit of normal. **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, bilirubin and/or gamma-glutamyl transferase levels. Baseline elevations of several liver function tests should preclude the use of riluzole. Because of the risk of hepatitis, serum transaminases, including ALT, should be measured before therapy with riluzole, and 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 upper limit of the normal range. Readministration of riluzole to patients in this situation cannot be recommended. *Neutropenia:* Patients should be warned to report any febrile illness to their physicians. *Interstitial lung disease:* Cases of interstitial lung disease have been reported in patients treated with riluzole, some of them were severe. If respiratory symptoms develop, chest radiography should be performed, and in case of findings suggestive of interstitial lung disease, riluzole should be discontinued immediately. In the majority of the reported cases, symptoms resolved after drug discontinuation and symptomatic treatment. *Renal impairment:* Studies at repeated doses have not been conducted in patients with impaired renal function. *Other:* The product contains liquid sorbitol (E420) therefore patients with rare hereditary problems of fructose intolerance should not take this medicine. **Interactions:** No interaction studies have been performed. *In vitro* studies using human liver microsomal preparations 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. Consult SPC for further information. **Pregnancy and Lactation:** Teglutik® is contraindicated in pregnancy and lactation. **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. No studies on the effects on the ability to drive and use machines have been performed. **Undesirable effects:** In phase III clinical studies conducted in ALS patients treated with riluzole, the most commonly reported adverse reactions were asthenia, nausea and abnormal liver function tests. *Very common:* nausea; abnormal liver function tests; asthenia. *Common:* headache, dizziness, oral paraesthesia and somnolence; tachycardia; diarrhoea, abdominal pain, vomiting; pain. *Uncommon:* anaemia; anaphylactoid reaction, angioedema; interstitial lung disease; pancreatitis. *Not known:* severe neutropenia; hepatitis. Consult SPC for further information. **Product Licence Number:** PL 20663/0002. **Product Licence Holder:** Italfarmaco S.A, C/ San Rafael, 3, Pol. Ind. Alcobendas, Alcobendas, Madrid 28108, Spain. **Basic NHS Price:** £100.00. **Legal Category:** POM. **Further information:** Martindale Pharma, Bampton Road, Romford, RM3 8UG. Tel: 01277266600. **Date of Preparation:** October 2015.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Martindale Pharma.
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