Prescribing Information
Emylif 50 mg orodispersible film

Consult Summary of Product Characteristics before prescribing.

Legal Category: POM

Marketing Authorisation number and basic NHS cost: PL 31654/0013 £168 for pack of 56 sachets.

Presentation: Each orodispersible film contains 50 mg of riluzole

Uses: Emylif is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

Dosage and administration:
The recommended daily dose in adults or older people is 100 mg (50 mg every 12 hours). No significant increased benefit can be expected from higher daily doses.

Method of administration:
Emylif is for oral administration.

Special populations:
Paediatric population: The safety and efficacy of Emylif for the treatment of ALS in the paediatric population have not been established. No data are available.
Elderly: Based on pharmacokinetic data, there are no special instructions for the use of riluzole in this population.
Hepatic impairment: Riluzole should be prescribed 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 (GGT) 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, 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.
Riluzole should be discontinued if the ALT levels increase to 5 times the ULN. There is no experience with dose reduction or rechallenge in patients who have developed an increase of ALT to 5 times ULN. Readministration of riluzole to patients in this situation cannot be recommended.
Renal impairment*:* Riluzole is not recommended for use in patients with impaired renal function, as studies at repeated doses have not been conducted in this population.

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:
Neutropenia: Patients should be warned to report any febrile illness to their physicians. The report of a febrile illness should prompt physicians to check white blood cell counts and to discontinue riluzole in case of neutropenia.
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 such as dry cough and/or dyspnoea, chest radiography should be performed, and in case of findings suggestive of interstitial lung disease (e.g. bilateral diffuse lung opacities), riluzole should be discontinued immediately. In the majority of the reported cases, symptoms resolved after medicinal product discontinuation and symptomatic treatment.
Oral hypoesthesia: In a single dose study in healthy subjects mild transient oral hypoesthesia has been reported. Median time to onset was 1 minute from the administration and median duration 40 minutes. In case oral hypoesthesia occurs, it is recommended to use caution if taking food until the symptom improves.
The swallowing safety of Emylif has not been evaluated in patients with severe sialorrhea or dysphagia. Caution should be exercised when administering Emylif to these patients.
Fertility: Fertility studies in rats revealed slight impairment of reproductive performance and fertility at doses of 15 mg/kg/day (which is higher than the therapeutic dose), probably due to sedation and lethargy.
Fructose: Each orodispersible film contains 2 mg. Fructose may damage teeth.
This medicinal product contains Sunset yellow FCF (E110), which may cause allergic reactions.

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.

Interactions:
There have been no clinical studies to evaluate the interactions of riluzole with other medicinal products.

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.

Side 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. Other commonly reported adverse reactions included oral hypoesthesia, headache, dizziness, oral paresthesia, somnolence, tachycardia, diarrhoea, abdominal pain, vomiting and pain.

Serious adverse reactions include anaphylactoid reaction, angioedema, interstitial lung disease, pancreatitis, severe neutropenia and hepatitis.

Consult the summary of product characteristics for other side effects or more information on those mentioned above.

Further information is available from:
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Adverse reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse reactions should also be reported to Zambon UK at drugsafetyUK@zambongroup.com or telephone: +44 (0) 800 0288 942