

**PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### Emylif 50 mg orodispersible film riluzole

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Emylif is and what it is used for
2. What you need to know before you take Emylif
3. How to take Emylif
4. Possible side effects
5. How to store Emylif
6. Contents of the pack and other information

#### **1. What Emylif is and what it is used for**

##### **What Emylif is**

The active substance in Emylif is riluzole which acts on the nervous system.

##### **What Emylif is used for**

Emylif is used in adult patients with amyotrophic lateral sclerosis (ALS).

ALS is a form of motor neurone disease where attacks of the nerve cells responsible for sending instructions to the muscles lead to weakness, muscle waste and paralysis.

The destruction of nerve cells in motor neurone disease may be caused by too much glutamate (a chemical messenger) in the brain and spinal cord. Emylif stops the release of glutamate and this may help in preventing the nerve cells being damaged.

Please consult your doctor for more information about ALS and the reason why this medicine has been prescribed for you.

#### **2. What you need to know before you take Emylif**

##### **Do not take Emylif**

- if you are **allergic** to riluzole or any of the other ingredients of this medicine (listed in section 6),
- if you have any **liver disease** or increased blood levels of some enzymes of the liver (transaminases),
- if you are **pregnant or breast-feeding**.

### **Warnings and precautions**

Talk to your doctor before taking Emylif:

- if you have any **liver problems**: yellowing of your skin or the white of your eyes (jaundice), itching all over, feeling sick, being sick
- if your **kidneys** are not working very well
- if you have any **fever**: it may be due to a low number of white blood cells which can cause an increased risk of infection
- if you have **excessive drooling** or **severe swallowing difficulties**.

**If any of the above applies to you, or if you are not sure, tell your doctor who will decide what to do.**

### **Children and adolescents**

If you are less than 18 years of age, the use of Emylif is not recommended because there is no information available in this population.

### **Other medicines and Emylif**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

### **Pregnancy, breast-feeding and fertility**

You **MUST NOT** take Emylif if you are or think you may be pregnant, or if you are breast-feeding.

If you think you may be pregnant, or if you intend to breast-feed, ask your doctor for advice before taking Emylif.

### **Driving and using machines**

You can drive or use any tools or machines, unless you feel dizzy or light-headed after taking this medicine.

### **Emylif contains:**

- 2 mg fructose in each orodispersible film. May be harmful to the teeth.
- sunset yellow FCF (E110). May cause allergic reactions.

## **3. How to take Emylif**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one orodispersible film, twice a day.

The orodispersible films should be taken by mouth, every 12 hours, at the same time of the day each day (e.g. in the morning and evening).

After taking this medicine, you can feel reduced oral sensitivity after 1 minute. Pay attention taking food until this feeling is over, which is usually in about 40 minutes.

## Method of administration:

Instructions for oral use are reported below.

### Step 1. Before Taking Emylif

- Ensure hands are clean and dry before handling Emylif so the film does not stick to your fingers.
- Check expiration date printed on foil sachet before use as shown in Figure 1.

**Do not** use Emylif if expired.

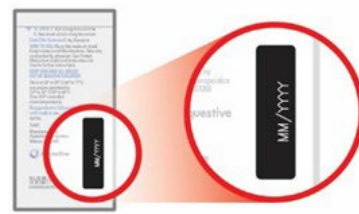


Figure 1

### Step 2. Open Sachet

- Fold foil sachet along solid line at top as shown in Figure 2.
- While keeping top of sachet folded over at solid line, tear down at the slit along the arrow on the side of the sachet to open.

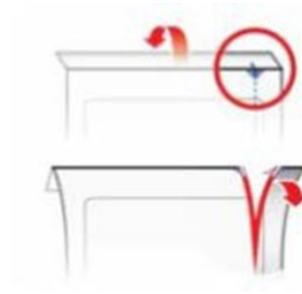


Figure 2

### Step 3. Remove Film

- Remove Emylif film from foil sachet. Each sachet contains one dose of Emylif.
- **Do not** fold Emylif film.

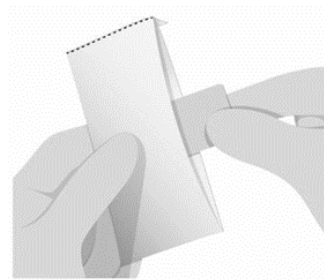


Figure 3

### Step 4. Place Film on Tongue

- Place Emylif film on top of the tongue as shown in Figure 4. The film will stick to the tongue and begin to dissolve.

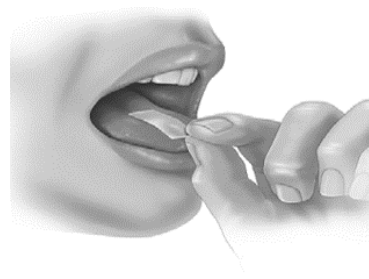


Figure 4

**Step 5. Close Mouth and Swallow Saliva Normally**

- Close mouth as shown in Figure 5 and swallow saliva normally as Emylif dissolves within 3 minutes.
- **Do not** take Emylif with liquids
- **Do not** chew, spit or talk while Emylif dissolves.



**Figure 5**

**Step 6. After the administration of Emylif, wash your hands**

**If you take more Emylif than you should**

If you take too many orodispersible film, contact your doctor or the nearest hospital emergency department immediately.

**If you forget to take Emylif**

If you forget to take your orodispersible film, leave out that dose completely and take the next orodispersible film at the usual time.

Do not take a double dose to make up for a forgotten orodispersible film.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**IMPORTANT**

**Tell your doctor immediately**

- if you experience any **fever** (increase in temperature) because Emylif may cause a decrease in the number of white blood cells. Your doctor may want to take a blood sample to check the number of white blood cells, which are important in fighting infections.
- if you experience any of the following symptoms: yellowing of your skin or the white of your eyes (jaundice), itching all over, feeling sick, being sick, as this may be signs of **liver disease** (hepatitis). Your doctor may do regular blood tests while you are taking Emylif to make sure that this does not occur.
- if you experience cough or difficulties in breathing, as this may be a sign of lung disease (called interstitial lung disease).

**Other side effects**

**Very common side effects** (may affect more than 1 in 10 people) of Emylif are:

- tiredness
- feeling sick
- increased blood levels of some enzymes of the liver (transaminases).
- reduced oral sensitivity

**Common side effects** (may affect up to 1 in 10 people) of Emylif are:

- dizziness
- numbness or tingling of the mouth
- vomiting
- sleepiness
- increase in heart beat
- diarrhoea
- headache
- abdominal pain
- pain

**Uncommon side effects** (may affect up to 1 in 100 people) of Emylif are:

- anaemia
- allergic reactions
- inflammation of the pancreas (pancreatitis).

**Not known:** frequency cannot be estimated from the available data

- rash

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Emylif**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the sachet and carton after “EXP” The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Emylif contains**

- The active substance is riluzole.
- The other ingredients are:  
polacrilix resin, pullulan (E1204), xylitol (E967), hypromellose (E464), glycerol (E422), glycerol mono-oleate, sucralose (E955), fructose, macrogol, flavor honey, xanthan gum, flavor lemon, sunset yellow FCF (E110), white ink (water purified, titanium dioxide (E171), propylene glycol (E1520), hypromellose (E464), isopropyl alcohol, ethanol and methanol).  
Trace levels of the antioxidant butylated hydroxytoluene (E321).

### **What Emylif looks like and content of the pack**

Orodispersible film:

Orange, rectangular-shaped, orally dissolving thin film (32 mm x 22 mm) with “R50” printed in white on one side.

Emylif is available in a pack of 14, 28, 56, 112, 140 orodispersible film to be taken orally.

Each carton box contains 14, 28, 56, 112, 140 sachets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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