Infographie COMPIÈGNE	*Version N°* **2**	*Type Article*	**Notice double**	*N° version Logo/Name* *N° version Country Ex.* *N° plan Dimensionnel* *N° plan positionnement* *Dimensions* *Taille mini caractères*	**N.A.** **N.A.** **COM-P606062** **COM-P606062-1f** **150 x 210 mm** **10 pts**	sanofi	
créé le *par* *modifié le* *par*	**07/03/2022** **DERIGNY C** **30/03/2022** **DERIGNY C**	*Nom du produit* *Référence article* *Dosage* *Quantité*	**Rilutek** **R796600** **50 mg** **cprs**			*Code sécurité* **R796600**	
Laboratoires *Pays*	**Sanofi** **Grande Bretagne/Ireland**	*Couleur* *Nbre/Réf.*	**1**	**NOIR**		*Numéro de pages* **1/4**	

PACKAGE LEAFLET: INFORMATION FOR THE USER

RILUTEK® 50 mg film-coated tablets

Riluzole

SANOFI

Is this leaflet hard to see or read? Phone 0800 035 2525 for help.

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 RILUTEK is and what it is used for

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

What RILUTEK is used for
RILUTEK is used in 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. RILUTEK 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 RILUTEK

Do not take RILUTEK
- 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 RILUTEK:
- 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 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 RILUTEK is not recommended because there is no information available in this population.

Other medicines and RILUTEK
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 RILUTEK 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 RILUTEK.

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

RILUTEK contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. How to take RILUTEK

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 tablet, twice a day.
- The tablets should be taken by mouth, every 12 hours, at the same time of the day each day (e.g. in the morning and evening).

If you take more RILUTEK than you should
If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately.

If you forget to take RILUTEK
If you forget to take your tablet, leave out that dose completely and take the next tablet at the usual time. **Do not** take a double dose to make up for a forgotten tablet.
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 RILUTEK 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 RILUTEK 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 RILUTEK are:
- tiredness
- feeling sick
- increased blood levels of some enzymes of the liver (transaminases)

Common side effects (may affect up to 1 in 10 people) of RILUTEK are:
- dizziness
- sleepiness
- headache
- numbness or tingling of the mouth
- increase in heart beat
- abdominal pain
- vomiting
- diarrhoea
- pain

Uncommon side effects (may affect up to 1 in 100 people) of RILUTEK are:
- anaemia
- allergic reactions
- inflammation of the pancreas (pancreatitis)

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.

United Kingdom
You can also report side effects directly via the Yellow Card Scheme at:
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 RILUTEK

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 carton and the blister after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Rilutek contains
- The active substance is riluzole.
- The other ingredients are:
  - Core: anhydrous dibasic calcium phosphate, micro crystalline cellulose, anhydrous colloidal silica, magnesium stearate, croscarmellose sodium
  - Coating: hypromellose, macrogol 6000, titanium dioxide (E171)

What Rilutek looks like and content of the pack
The tablets are film-coated, capsule-shaped and white. Each tablet contains 50 mg of riluzole and is engraved with "RPR 202" on one side.
RILUTEK is available in a pack of 56 tablets to be taken orally.

Marketing Authorisation Holder and Manufacturer
Sanofi Mature IP
54 rue La Boétie
75008 Paris
France

Manufacturer
Opella Healthcare International SAS
56, Route de Choisy
60200 Compiègne
France

This leaflet was last revised in 04/2022

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

United Kingdom
Sanofi
Tel: 0800 035 2525
Email: uk-medicalinformation@sanofi.com