EMEA/H/C/000109

EPAR summary for the public

Rilutek

riluzole

This is a summary of the European public assessment report (EPAR) for Rilutek. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Rilutek.

What is Rilutek?

Rilutek is a medicine containing the active substance riluzole. It is available as 50 mg tablets.

What is Rilutek used for?

Rilutek is used in patients with amyotrophic lateral sclerosis (ALS). ALS is a form of motor neuron disease where the nerve cells responsible for sending instructions to the muscles gradually deteriorate, leading to weakness, muscle wasting and paralysis. Rilutek is used to extend the patient's life or to delay the need for mechanical ventilation.

Rilutek should not be used in patients with any other form of motor neuron disease.

The medicine can only be obtained with a prescription.

How is Rilutek used?

Treatment with Rilutek should only be started by a specialist doctor with experience in the management of motor neuron diseases. The recommended dose is 100 mg per day (given as one 50 mg tablet every 12 hours). For more information, see the package leaflet.

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How does Rilutek work?

The active substance in Rilutek, riluzole, acts on the nervous system. The exact way in which it works in ALS is not known. It is thought that the destruction of nerve cells in motor neuron disease may be caused by too much of the neurotransmitter glutamate. Neurotransmitters are substances that nerve cells use to communicate with neighbouring cells. Riluzole stops the release of glutamate and this may help in preventing the nerve cells being damaged.

How has Rilutek been studied?

Rilutek has been compared with placebo (a dummy treatment) in three studies involving a total of 1,282 patients. One of these studies was in older patients (over 75) and in patients with advanced disease. Across the studies, Rilutek was given as 50, 100 or 200 mg per day, and for up to 18 months. The main measure of effectiveness was the average survival time.

What benefit has Rilutek shown during the studies?

The average survival time was significantly longer for patients who received Rilutek compared with patients who received placebo. Looking at the results of the three studies together, over 18 months, patients who received Rilutek 100 mg/day had an average survival time that was about 2 months longer than the survival time for patients who received placebo. Rilutek 50 mg/day was no more effective than placebo and 200 mg/day was no more effective than 100 mg/day. The medicine was not more effective than placebo in the late stages of ALS.

What is the risk associated with Rilutek?

The most common side effects seen with Rilutek (in more than 1 patient in 10) are nausea (feeling sick), asthenia (weakness) and abnormal liver tests. For the full list of all side effects reported with Rilutek, see the package leaflet.

Rilutek must not be used in patients who have liver disease or who have abnormally high levels of liver enzymes. Rilutek must also not be given to women who are pregnant or breastfeeding. For the full list of restrictions, see the package leaflet.

Why has Rilutek been approved?

The CHMP decided that Rilutek's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Rilutek

The European Commission granted a marketing authorisation valid throughout the European Union for Rilutek on 10 June 1996.

The full EPAR for Rilutek can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Rilutek, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2016.