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EPAR summary for the public

Riluzole Zentiva

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This is a summary of the European public assessment report (EPAR) for Riluzole Zentiva. 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 Riluzole Zentiva.

What is Riluzole Zentiva?

Riluzole Zentiva is a medicine containing the active substance riluzole. It is available as tablets (50 mg).

This medicine is the same as Rilutek, which is already authorised in the European Union (EU). The company that makes Rilutek has agreed that its scientific data can be used for Riluzole Zentiva ('informed consent').

What is Riluzole Zentiva used for?

Riluzole Zentiva 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. Riluzole Zentiva is used to extend the patient's life, or the time before they need to use mechanical ventilation.

Riluzole Zentiva should not be used in patients with any other form of motor neurone disease.

The medicine can only be obtained with a prescription.

How is Riluzole Zentiva used?

Treatment with Riluzole Zentiva should only be started by a specialist doctor with experience in the management of motor neurone diseases. In adult and elderly patients, it is given as 100 mg a day (50 mg every 12 hours). For more information please see the package leaflet.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

How does Riluzole Zentiva work?

The active substance in Riluzole Zentiva, 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 neurone disease may be caused by too much glutamate, a neurotransmitter (chemical messenger). Riluzole stops the release of glutamate and this may help in preventing the nerve cells being damaged.

How has Riluzole Zentiva been studied?

The effectiveness of Riluzole Zentiva has been compared with that of 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, Riluzole Zentiva 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 Riluzole Zentiva shown during the studies?

The average survival time was significantly longer for patients who received Riluzole Zentiva compared with patients who received placebo. Looking at the results of the three studies together, over 18 months, patients who received Riluzole Zentiva 100 mg/day had an average survival time that was about two months longer than the survival time for patients who received placebo. Riluzole Zentiva 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 Riluzole Zentiva?

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

Riluzole Zentiva must not be used in people who are hypersensitive (allergic) to riluzole or any of the other ingredients. Riluzole Zentiva must not be used in patients who have liver disease or who have abnormally high levels of liver enzymes. Riluzole Zentiva must also not be given to women who are pregnant or breast-feeding.

Why has Riluzole Zentiva been approved?

The CHMP decided that Riluzole Zentiva's benefits are greater than its risks to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis. They noted that there is no evidence that Riluzole Zentiva exerts a therapeutic effect on motor function, lung function, fasciculations, muscle strength and motor symptoms, and that it has not been shown to be effective in the late stages of ALS. The Committee recommended that Riluzole Zentiva be given marketing authorisation.

Other information about Riluzole Zentiva

The European Commission granted a marketing authorisation valid throughout the European Union for Riluzole Zentiva on 7 May 2012.

The full EPAR for Riluzole Zentiva 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 Riluzole Zentiva, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2012.