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Cenrifki (*tolebrutinib*)

A plain-language overview of Cenrifki and why it is authorised in the EU

What is Cenrifki and what is it used for?

Cenrifki is a medicine used to treat adults with an advanced form of multiple sclerosis (MS) known as secondary progressive MS.

It is used in patients who have not had relapses in the last two years.

Cenrifki contains the active substance tolebrutinib.

How is Cenrifki used?

The medicine can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the management of MS.

Cenrifki is available as tablets that should be taken once a day with a meal. The doctor will check the patient's liver function before starting treatment. Treatment should not be started in patients who have abnormal results from these tests. Liver function should be monitored regularly after treatment has started; treatment may have to be temporarily interrupted or discontinued if liver function decreases.

For more information about using Cenrifki, see the package leaflet or contact your doctor or pharmacist.

How does Cenrifki work?

In MS, the immune system (the body's defences) attacks and damages the protective sheath around the nerves in the brain and spinal cord.

The active substance in Cenrifki, tolebrutinib, blocks the action of an enzyme known as Bruton's tyrosine kinase (BTK). BTK is important for the growth of a type of immune cells called B cells. In MS, B cells play a key role in driving inflammation in the central nervous system by activating immune responses and producing substances that damage nerve cells and their protective myelin sheath. By blocking BTK, tolebrutinib reduces the activation of these B cells.

In addition, BTK is involved in the activity of microglia and macrophages, which are other immune cells found in the brain and spinal cord and are known to contribute to chronic inflammation and damage in

MS. By blocking BTK in these cells, tolebrutinib is expected to reduce inflammation and help slow disease progression.

What benefits of Cenrifki have been shown in studies?

Cenrifki was shown to be more effective than placebo (a dummy treatment) at delaying the progression of the disease in a main study involving 1,131 patients with secondary progressive MS who did not have relapses in the last two years.

Disease progression was defined as worsening of the disease which is not related to a relapse and lasted for at least 6 months; it was measured using a standard scale called the expanded disability status scale (EDSS). During the study, 26.9% of patients receiving treatment with Cenrifki experienced disease progression compared with 37.2% of patients taking placebo.

Studies carried out with Cenrifki are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Cenrifki?

For the full list of side effects and restrictions with Cenrifki, see the package leaflet.

The most common side effects with Cenrifki (which may affect more than 1 in 10 people) include COVID-19 and upper respiratory tract (nose and throat) infections.

Some side effects can be serious. The most frequent serious side effect with this medicine is COVID-19 pneumonia (infection of the lungs) which may affect more than 1 in 10 people. Liver injury can occur with Cenrifki, especially during the first months of treatment, and regular blood tests are required to check liver function.

Cenrifki must not be used in patients with moderate to severe liver problems, certain abnormal liver blood test results, or a severely weakened immune system.

Why is Cenrifki authorised in the EU?

At the time of approval of Cenrifki, there were limited treatment options for patients with progressive MS. Cenrifki was shown to delay the progression of disability in secondary progressive MS. The main safety concern is liver injury, which can be managed through early detection and close monitoring of liver function.

The European Medicines Agency therefore decided that Cenrifki's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Cenrifki?

The company that markets Cenrifki will provide educational material for doctors who are expected to prescribe this medicine. These will include information about the risk of liver problems with Cenrifki and the need to monitor liver function before and during treatment. A card will also be given to patients about the risk of liver injury, the need for liver monitoring and to contact their doctor if they develop symptoms of liver injury.

These materials may be made available by national competent authorities on their websites. A list of national repositories is available on the EMA website.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Cenrifki have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Cenrifki are continuously monitored. Suspected side effects reported with Cenrifki are carefully evaluated and any necessary action taken to protect patients.

Other information about Cenrifki

Cenrifki received a marketing authorisation valid throughout the EU on 19-06-2026.

Further information on Cenrifki, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/cenrifki.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 06-2026.