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Mayzent (*siponimod*)

An overview of Mayzent and why it is authorised in the EU

What is Mayzent and what is it used for?

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

It is used in patients with active disease, which means that patients still have relapses or signs of inflammation can be seen in scans.

Mayzent contains the active substance siponimod.

How is Mayzent used?

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

Mayzent is available as tablets and should be taken once a day. Treatment is started with a dose of 0.25 mg daily for two days. The dose is then progressively increased to reach the 'maintenance' dose on the sixth day. The maintenance dose is either 1 mg or 2 mg daily, depending on how quickly the patient's body can process the medicine. This is determined by the use of a blood or saliva test to measure the activity of the patient's liver enzyme CYP2C9.

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

How does Mayzent 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 Mayzent, siponimod, blocks the action of some receptors (targets) on cells called sphingosine-1-phosphate receptors, which are involved in the movement of lymphocytes (immune cells) around the body. By attaching to these receptors, siponimod stops lymphocytes from travelling from the lymph nodes towards the brain and spinal cord, thus limiting the damage they cause in MS.

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What benefits of Mayzent have been shown in studies?

Mayzent was shown to be effective at delaying the progression of the disease in a 3-year main study involving 1,651 patients with secondary progressive MS, of whom 779 had active disease with a relapse within 2 years or other signs of inflammation in scans.

Disease progression was defined as worsening of the disease that is independent from a relapse and is maintained over at least 3 months, as assessed using a standard scale called EDSS. During the study, 25% of patients with active secondary progressive MS taking Mayzent had disease progression compared with 35% of patients taking placebo (a dummy treatment).

What are the risks associated with Mayzent?

The most common side effects with Mayzent (which may affect more than 1 in 10 people) are headache and hypertension (high blood pressure).

Mayzent must not be used in patients who are hypersensitive (allergic) to siponimod, or to peanut, soya or any of the other ingredients of the medicine. The medicine must also not be used in patients who previously had certain severe infections (known as progressive multifocal leukoencephalopathy or cryptococcal meningitis). Mayzent must also not be used in patients with cancer and certain immune disorders due to its effect on the immune system. It must not be used in patients who have recently had a stroke and in patients with certain heart disorders (because of its effects on heart rate and blood pressure), severe liver disorders and in pregnant women and women who can become pregnant and are not using effective contraception.

Mayzent must also not be used in patients who have inherited a gene known as CYP2C9*3 from both parents, which makes them unable to process the medicine fast enough. For the full list of side effects and restrictions of Mayzent, see the package leaflet.

Why is Mayzent authorised in the EU?

Mayzent was effective at delaying the progression of secondary progressive MS in patients with active disease; however, the beneficial effects of the medicine were not demonstrated in patients without an active disease. The European Medicines Agency therefore decided that Mayzent should only be used in patients whose disease is active with signs of inflammation.

The side effects with Mayzent are similar to those with another medicine (fingolimod) for MS working in a similar way, and are considered acceptable.

The Agency therefore decided that Mayzent'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 Mayzent?

The company that markets Mayzent will ensure that doctors expected to prescribe the medicine receive educational materials, including a checklist covering the necessary screening, pre-treatment and long-term monitoring of patients. The materials will include a guide for patients with key safety information about Mayzent, as well as a pregnancy reminder card for women who can become pregnant.

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

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

Other information about Mayzent

Mayzent received a marketing authorisation valid throughout the EU on 13 January 2020.

Further information on Mayzent can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/Mayzent.

This overview was last updated in 01-2020.