

## **What is Mayzent?**

Mayzent contains the active substance siponimod. Siponimod belongs to a group of medicines called sphingosine-1-phosphate (S1P) receptor modulators. It is known as a disease modifying therapy (DMT) and targets the immune system to reduce relapses and slow disease progression.

## **How does Mayzent work?**

Mayzent helps to protect the central nervous system (CNS) from attacks by the body's own immune system. It does this by:

- making some white blood cells (called lymphocytes) less able to move freely within the body, and
- stopping these cells from reaching the brain and spinal cord. This reduces nerve damage caused by SPMS and as a result Mayzent helps to slow down the effects of the disease activity (such as worsening disability, brain lesions and relapses).

## **Who should take Mayzent?**

Mayzent is used to treat adults with secondary progressive multiple sclerosis (SPMS) with active disease. Active disease in SPMS is when there are still relapses or when MRI (magnetic resonance imaging) results show signs of inflammation.

## **How is Mayzent administered?**

Mayzent is taken orally as a once daily tablet. The recommended dose is 2 mg (one tablet of 2 mg Mayzent) with or without food. Your doctor may instruct you to take only 1 mg once daily (one tablet of Mayzent 1 mg or four tablets of Mayzent 0.25 mg) if the saliva test performed before the start of treatment showed that your body breaks down Mayzent slowly.

You will be given a titration pack, with which your dose will be gradually increased over 5 days. On day 6, you will switch to your regular treatment dose. The purpose of the titration phase is to reduce the risk of side effects on your heart at the start of treatment.

For some people, depending on what your doctor recommends, you may be able to start taking Mayzent at home, without supervision. However, if you have certain heart conditions, your doctor may ask you to attend the hospital on the first day you take Mayzent. Your doctor and a member of the Novartis nurse team will monitor you for at least 6 hours after you take the first tablet. They will measure your heart rate using an ECG and check your blood pressure and heart rate.

## What are the side effects from taking Mayzent?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### Some side effects could be serious

**Common** (may affect up to 1 in 10 people)

- Rash with small fluid-filled blisters, appearing on reddened skin (symptoms of a viral infection called herpes zoster that can be severe)
- A type of skin cancer called basal cell carcinoma (BCC) which often appears as a pearly nodule, though it can also take other forms.
- Fever, sore throat and/or mouth ulcers due to infection (lymphopenia)
- Convulsions, fits
- Visual disturbances such as a shadow or a blind spot in the centre of vision, blurred vision,
- problems seeing colours or details (symptoms of macular oedema, which is a swelling in the
- macular area of the retina at the back of the eye)
- Irregular heartbeat (atrioventricular block)
- Slow heartbeat (bradycardia)

If you get any of these, tell your doctor straight away.

**Not known** (frequency cannot be estimated from the available data)

Cryptococcal infections (a type of fungal infection), including cryptococcal meningitis with symptoms such as headache together with stiff neck, sensitivity to light, feeling sick (nausea) or confusion.

### Other possible side effects

Other side effects include those listed below.

**Very common** (may affect more than 1 in 10 people)

- headache
- high blood pressure (hypertension), sometimes with symptoms such as headache and dizziness
- blood test results showing increased liver enzyme levels

**Common** (may affect up to 1 in 10 people)

- new moles
- dizziness
- involuntary shaking of the body (tremor)
- diarrhoea
- feeling sick (nausea)
- pain in hands or feet
- swollen hands, ankles, legs or feet (peripheral oedema)

- weakness (asthenia)
- lung function test results showing decreased function

### **What are the findings from Mayzent's clinical trials?**

Mayzent was studied in a large trial of patients with SPMS. The trial was designed to make sure it included a broad range of patients with SPMS. The trial showed that Mayzent can slow down physical disability progression, reduce relapses and reduce the chance of brain function getting worse, which can affect thinking speed and problem solving.

More details on this clinical trial can be found here:

- [www.clinicaltrials.gov](http://www.clinicaltrials.gov) – once you are on this website, type **NCT01665144** into the search box and click “**Search**”.

Please consult your healthcare team if you have any further questions about siponimod.

### **When was Mayzent made available?**

From 1st February 2022, Mayzent is available under the High-Tech Drug Scheme in Ireland.

As of May 28, 2021, a total of 2897 patients received siponimod in clinical trials including open-label extensions and, as of September 25, 2021, more than 8000 patients in the post-marketing experience received siponimod