Package leaflet: Information for the patient

Mayzent 0.25 mg film-coated tablets
Mayzent 1 mg film-coated tablets
Mayzent 2 mg film-coated tablets
siponimod

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mayzent is and what it is used for
2. What you need to know before you take Mayzent
3. How to take Mayzent
4. Possible side effects
5. How to store Mayzent
6. Contents of the pack and other information

1. What Mayzent is and what it is used for

What Mayzent is
Mayzent contains the active substance siponimod. Siponimod belongs to a group of medicines called sphingosine-1-phosphate (S1P) receptor modulators.

What Mayzent is used for
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 Mayzent works
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).

2. What you need to know before you take Mayzent

Do not take Mayzent
- if you are allergic to siponimod, peanut, soya or any of the other ingredients of this medicine (listed in section 6).
- if you have an immunodeficiency syndrome.
- if you have ever had progressive multifocal leukoencephalopathy or cryptococcal meningitis.
- if you have an active cancer.
- if you have severe liver problems.

- if, in the last 6 months, you have had a heart attack, unstable angina, stroke or certain types of heart failure.
- if you have certain types of irregular or abnormal heartbeat (arrhythmia) and you do not have a pacemaker.
- if blood tests show that your body cannot break down this medicine well enough, you should not take it (see "Blood tests before and during treatment" below).
- if you are pregnant or could become pregnant and are not using effective contraception.

Warnings and precautions
Talk to your doctor **before** taking Mayzent:
- if you have an infection or if your immune system does not work properly (for example due to a disease or to medicines that suppress the immune system; see also "Other medicines and Mayzent").
- if you have never had chickenpox and have not been vaccinated against it. You may be at greater risk of complications if you develop chickenpox during Mayzent treatment. Your doctor may want to vaccinate you against chickenpox before you start treatment.
- if you are planning to have any vaccinations. Your doctor will advise you on this (see "Other medicines and Mayzent").
- if you have ever had, or have, difficulties with your vision (in particular a condition called macular oedema) or an infection or inflammation of the eye (uveitis). Your doctor may want you to have eye examinations before you start treatment and regularly while you are on treatment. Mayzent can cause a swelling in the macula (the area of the eye that enables you to see shapes, colours and details) known as macular oedema. Your chance of developing macular oedema is higher if you have had it before or if you have ever had uveitis (an inflammation of the eye).
- if you have diabetes. The chance of developing macular oedema (see above) is higher in patients with diabetes.
- if you have ever had any of the following conditions (even if you are receiving treatment for them): severe heart disease, irregular or abnormal heartbeat (arrhythmia), stroke or other disease related to the blood vessels in the brain, a slow heart rate, fainting, disturbance of heart rhythm (indicated by abnormal ECG results).
- if you have severe breathing problems when sleeping (sleep apnoea).
- if you have high blood pressure that cannot be controlled by medicines. Your blood pressure will need to be checked regularly.
- if you have ever had liver problems. Your doctor may want to perform blood tests to check your liver function before prescribing Mayzent.
- if you could become pregnant, because siponimod can harm the unborn baby when used during pregnancy. Before you start treatment, your doctor will explain the risk and ask you to do a pregnancy test to ensure that you are not pregnant. You must use effective contraception during treatment and for at least 10 days after stopping treatment (see "Pregnancy, breast-feeding and fertility").

If any of the above applies to you, tell your doctor **before** taking Mayzent.

Look out for the following while taking Mayzent
If you get any of the following while taking Mayzent, **tell your doctor immediately** because it could be serious:
- if you have an infection. Mayzent lowers the number of white cells in your blood. White blood cells fight infection, so you may get infections more easily while you are taking Mayzent (and up to 3 to 4 weeks after you stop taking it). These could be serious and possibly even life-threatening.
- if you think your multiple sclerosis (MS) is getting worse or if you notice any new or unusual symptoms. A rare brain infection called progressive multifocal leukoencephalopathy (PML) can cause symptoms similar to SPMS. It can occur in patients taking medicines like Mayzent and other medicines used for treating MS. If PML is confirmed, your doctor will stop treatment with Mayzent. Some people can get a reaction as Mayzent is removed from the body. This reaction

(known as immune reconstitution inflammatory syndrome or IRIS) may lead to your condition getting worse, including worsening of brain function.
- if you have fever, feel like you have flu or have a headache together with a stiff neck, sensitivity to light, nausea or confusion. These may be symptoms of meningitis and/or encephalitis caused by a viral or fungal infection (such as cryptococcal meningitis).
- if you have changes in your vision, for example if the centre of your vision becomes blurred or has shadows, a blind spot develops in the centre of your vision, or you have problems seeing colours or fine detail. These may be symptoms of macular oedema. You may not notice any symptoms in the early stages of macular oedema, and it can cause some of the same visual symptoms as an MS attack (optic neuritis). Your doctor may want you to have an eye examination 3 or 4 months after starting treatment and possibly again later. If macular oedema is confirmed, your doctor may advise you to stop Mayzent treatment.
- if you have symptoms such as sudden onset of severe headache, confusion, seizures and vision changes. These may be symptoms of a condition called posterior reversible encephalopathy syndrome (PRES).
- if you have symptoms such as unexplained nausea, vomiting, abdominal pain, tiredness, yellowing of the skin or whites of the eyes or abnormally dark urine. These may be symptoms of liver problems.
- if you notice any skin nodules (e.g. shiny, pearly nodules), patches or open sores that do not heal within weeks.

Slow heart rate (bradycardia) and irregular heartbeat
During the first days of treatment, Mayzent can cause the heart rate to slow down (bradycardia). You may not feel anything or you may feel dizzy or tired. It may also cause your heartbeat to become irregular at the beginning of treatment. If anything indicates that you may be at higher risk of suffering from these effects, your doctor may decide to monitor you more closely at the start of treatment, refer you first to a heart specialist (cardiologist), or choose not to give you Mayzent.

Tests before and during treatment
How quickly this medicine is broken down (metabolised) in the body varies from patient to patient and different people therefore require different doses. Your doctor will perform a blood or saliva test before you start treatment to determine which dose is best for you. In rare cases, the test result may indicate that you should not take Mayzent.

- **Blood count**

The desired effect of Mayzent treatment is to reduce the amount of white blood cells in your blood. This will usually go back to normal within 3-4 weeks of stopping treatment. If you need to have any blood tests, tell the doctor that you are taking Mayzent. Otherwise, it may not be possible for the doctor to understand the results of the test, and for certain types of blood test your doctor may need to take more blood than usual.

Before you start Mayzent, your doctor will confirm whether you have enough white blood cells in your blood and may want to repeat a check regularly. In case you do not have enough white blood cells, your doctor may need to stop or reduce your Mayzent dose.

Before the start of treatment your blood will also be tested to check how well your liver is working.

Skin cancer
Skin cancers have been reported in MS patients treated with Mayzent. Talk to your doctor straight away if you notice any skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (e.g. unusual moles) with a change in colour, shape or size over time. Before you start Mayzent, a skin examination is required to check whether you have any skin nodules. Your doctor will also carry out regular skin examinations during your treatment with Mayzent. If you develop problems with your skin, your doctor may refer you to a dermatologist, who after consultation may decide that it is important for you to be seen on a regular basis.

Exposure to the sun and protection against the sun
Mayzent weakens your immune system. This may increase your risk of developing skin cancer. You should limit your exposure to the sun and UV rays by:
- wearing appropriate protective clothing.
- regularly applying sunscreen with a high degree of UV protection.

Worsening of MS after stopping Mayzent treatment
Do not stop taking Mayzent or change your dose without talking to your doctor first.

Tell your doctor straight away if you think your MS worsens after you have stopped treatment with Mayzent (see "If you stop taking Mayzent" in section 3).

Elderly patients (65 years of age and above)
There is no experience with Mayzent in elderly patients. Talk to your doctor if you have any concerns.

Children and adolescents
Do not give this medicine to children and adolescents below 18 years of age because it has not yet been studied in this age group.

Other medicines and Mayzent
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Make sure to tell your doctor if you are taking or receiving any of the following medicines or therapies:
- medicines for an irregular heartbeat, such as amiodarone, procainamide, quinidine or sotalol. Your doctor may decide not to prescribe Mayzent because it could intensify the effect on irregular heartbeat.
- medicines that slow down the heartbeat, such as diltiazem or verapamil (which belong to a group of medicines called calcium channel blockers), digoxin or ivabradine. Your doctor may refer you to a heart specialist, as your medicines may need to be changed because Mayzent may also slow down your heartbeat in the first days of treatment. If you are taking a beta blocker, such as atenolol or propranolol, your doctor may ask you to temporarily stop your beta-blocker treatment until you have reached your full daily dose of Mayzent.
- medicines that affect the immune system, such as chemotherapy, immunosuppressants or other medicines to treat MS. Your doctor may ask you to stop taking these to avoid an increased effect on the immune system.
- vaccines. If you need to have a vaccination, talk to your doctor first. During and for 4 weeks after stopping treatment with Mayzent, you should not be given certain types of vaccine (called live attenuated vaccines) as they could trigger the infection that they were supposed to prevent (see section 2).
- strong CYP2C9 inhibitors are anticipated to increase the levels of Mayzent in the blood and are not recommended to be taken in combination with Mayzent. Your doctor will advise you on this.
- carbamazepine and certain other medicines can lower the levels of Mayzent in your blood and can therefore stop it from working properly. Your doctor will advise you on this.
- modafinil and certain other medicines can lower the levels of Mayzent in the blood of certain patients and can therefore stop it from working properly. Your doctor will advise you on this if this is relevant for you.
- phototherapy with UV radiation or PUVA photochemotherapy. UV therapy during Mayzent treatment may increase your risk of developing skin cancer.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Do not use Mayzent during pregnancy, if you are trying to become pregnant or if you are a woman who could become pregnant and you are not using effective contraception. If Mayzent is used during

pregnancy, there is a risk of harm to the unborn baby. If you are a woman who could become pregnant, your doctor will inform you about this risk before you start treatment with Mayzent and will ask you to do a pregnancy test in order to ensure that you are not pregnant. You must use effective contraception while taking Mayzent and for at least 10 days after you stop taking it to avoid becoming pregnant. Ask your doctor about reliable methods of contraception.

If you do become pregnant while taking Mayzent, tell your doctor straight away. Your doctor will decide to stop treatment (see "If you stop taking Mayzent" in section 3). Specialised pre-natal monitoring will be performed.

You should not breast-feed while you are taking Mayzent. Mayzent may pass into breast milk and there is a risk of serious side effects for the baby.

Driving and using machines
Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. Mayzent is not expected to affect your ability to drive and use machines when you are on your regular treatment dose. At the start of treatment you may occasionally feel dizzy. On your first day of treatment with Mayzent, therefore, you should not drive or use machines.

Mayzent contains lactose and soya lecithin
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

If you are allergic to peanut or soya, do not use this medicine.

3. How to take Mayzent

Treatment with Mayzent will be overseen by a doctor who is experienced in the treatment of MS.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

How much Mayzent to take
Starting treatment
You will be given a titration pack, with which your dose will be gradually increased over 5 days. Follow the instructions on the pack (see also the "Titration pack" table).

The purpose of the titration phase is to reduce the risk of side effects on your heart at the start of treatment. Your doctor may monitor you closely at the start of treatment if you are at risk of your heartbeat becoming slower or irregular.

Titration pack

Day	Dose	Number of Mayzent 0.25 mg tablets to take
Day 1	0.25 mg	1 tablet
Day 2	0.25 mg	1 tablet
Day 3	0.5 mg	2 tablets
Day 4	0.75 mg	3 tablets
Day 5	1.25 mg	5 tablets

On day 6, you will switch to your regular treatment dose.

On the first 6 days of treatment, it is recommended that you take the tablets in the morning with or without food.

Treatment dose
The recommended dose is 2 mg once daily (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 blood test performed before the start of treatment showed that your body breaks down Mayzent slowly (see "Tests before and during treatment"). If this applies to you, note that it is nevertheless safe for you to take five 0.25 mg tablets on day 5 of the titration period as indicated above.

Mayzent is for oral use. Take the tablet with water.

If you take more Mayzent than you should
If you have taken too many Mayzent tablets, or if you take your first tablet from the treatment dose pack instead of the titration pack by mistake, call your doctor straight away. Your doctor may decide to keep you under observation.

If you forget to take Mayzent
During the first 6 days of treatment, if you have forgotten to take your dose on one day, call your doctor before you take the next dose. Your doctor will need to prescribe a new titration pack. You will have to restart at day 1.

If you miss a dose when you are on the regular treatment dose (day 7 onwards), take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose. If you forget to take Mayzent for 4 or more days in a row, call your doctor before you take the next dose. Your doctor will need to prescribe a new titration pack and you will have to restart treatment at day 1.

If you stop taking Mayzent
Do not stop taking Mayzent or change your dose without talking to your doctor first.

Mayzent will stay in your body for up to 10 days after you stop taking it. Your white blood cell (lymphocyte) count may remain low for up to 3 to 4 weeks after you stop taking Mayzent. The side effects described in this leaflet may still occur during this period (see "Possible side effects" in section 4).

If you have to restart Mayzent more than 4 days after you stopped taking it, your doctor will prescribe a new titration pack and you will have to restart treatment at day 1 again.

Tell your doctor straight away if you think your MS worsens after you have stopped treatment with Mayzent.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Serious side effects
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)

Uncommon (may affect up to 1 in 100 people)
- A type of skin cancer called squamous cell carcinoma which may present as a firm red nodule, a sore with a crust, or a new sore on an existing scar
- A type of skin cancer called malignant melanoma which usually develops from an unusual mole. Possible signs of melanoma include moles which may change size, shape, elevation or colour over time, or new moles. The moles may itch, bleed or ulcerate.

Rare (may affect up to 1 in 1 000 people)
- A brain infection called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to MS such as weakness or visual changes, memory loss, trouble thinking or difficulty walking.
- Inflammatory disorder after stopping Mayzent treatment (known as immune reconstitution inflammatory syndrome or IRIS).

Not known (frequency cannot be estimated from the available data)
- Cryptococcal infections (a type of fungal infection) or viral infections (caused by herpes or varicella zoster virus), including meningitis and/or encephalitis with symptoms such as headache together with stiff neck, sensitivity to light, feeling sick (nausea) or confusion

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

Other side effects
Other side effects include those listed below. If any of these side effects becomes severe, **tell your doctor or pharmacist**.

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mayzent

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton/blister foil after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Mayzent contains

- The active substance is siponimod.

Mayzent 0.25 mg film-coated tablets

- Each tablet contains 0.25 mg siponimod (as siponimod fumaric acid).
- The other ingredients are:
  Tablet core: Lactose monohydrate (see "Mayzent contains lactose and soya lecithin" in section 2), microcrystalline cellulose, crospovidone, glycerol dibehenate, colloidal anhydrous silica.
  Tablet coating: Polyvinyl alcohol, titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172), talc, soya lecithin (see "Mayzent contains lactose and soya lecithin" in section 2), xanthan gum.

Mayzent 1 mg film-coated tablets

- Each tablet contains 1 mg siponimod (as siponimod fumaric acid).
- The other ingredients are:
  Tablet core: Lactose monohydrate (see "Mayzent contains lactose and soya lecithin" in section 2), microcrystalline cellulose, crospovidone, glycerol dibehenate, colloidal anhydrous silica.
  Tablet coating: Polyvinyl alcohol, titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172), talc, soya lecithin (see "Mayzent contains lactose and soya lecithin" in section 2), xanthan gum.

Mayzent 2 mg film-coated tablets

- Each tablet contains 2 mg siponimod (as siponimod fumaric acid).
- The other ingredients are:
  Tablet core: Lactose monohydrate (see "Mayzent contains lactose and soya lecithin" in section 2), microcrystalline cellulose, crospovidone, glycerol dibehenate, colloidal anhydrous silica.
  Tablet coating: Polyvinyl alcohol, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), talc, soya lecithin (see "Mayzent contains lactose and soya lecithin" in section 2), xanthan gum.

What Mayzent looks like and contents of the pack

Mayzent 0.25 mg film-coated tablets are pale red, round film-coated tablets with the company logo on one side and "T" on the other side.

Mayzent 1 mg film-coated tablets are violet white, round film-coated tablets with the company logo on one side and "L" on the other side.

Mayzent 2 mg film-coated tablets are pale yellow, round film-coated tablets with the company logo on one side and “II” on the other side.

Mayzent 0.25 mg film-coated tablets are available in the following pack sizes:
- Titration pack as wallet containing 12 tablets, and
- Packs containing 84 or 120 tablets

Mayzent 1 mg film-coated tablets are available in packs containing 28 or 98 tablets.

Mayzent 2 mg film-coated tablets are available in packs containing 14, 28 or 98 tablets.

Not all pack sizes may be marketed.

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