مايزنت (سيبونيمود):
معلومات للمريضات ممن لديهن القدرة على الحَمْل

دليل المرضى

"تم اعتماد هذا المستند من هيئة الغذاء و الدواء في المملكة العربية السعودية"

هذه المادة التعليمية ضرورية لضمان الاستخدام الآمن للمنتج ومعرفة المخاطر المحتملة.

MAYZENT (siponimod): Information for female patients of childbearing potential

Patient Reminder Card

"This RMP Material is Approved by the SFDA"

This educational material is essential to ensure the safe use of the product and appropriate management of the important risks.

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قبل بدء العلاج بعقار مايزنت

يجب عدم استخدام عقار مايزنت للسيدات الحوامل أو اللاتي لديهن القدرة على الحَمْل ممن لا يستخدمن وسائل فعَّالة لمنع الحَمْل.

قبل بدء العلاج يجب إجراء اختبار حَمْل للسيدات ممن لديهن القدرة على الحَمْل، على أن يتحقق الطبيب من كون النتيجة سلبية.

تحدَّثي مع طبيبكِ بخصوص وسائل منع الحَمْل الموثوقة التي عليكِ استخدامها أثناء العلاج ولمدة ١٠ أيام على الأقل بعد إيقافكِ العلاج بعقار سيبونيمود.

يُرجى قراءة نشرة معلومات عقار مايزنت الموجودة داخل العبوة.

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Before starting MAYZENT

MAYZENT should not be used in pregnant women or in women of childbearing potential not using effective contraception.

Before starting treatment, a pregnancy test must be conducted in women of childbearing potential, and a negative result verified by a doctor.

Talk with your doctor about reliable methods of birth control that you should use during treatment and for at least 10 days after you stop siponimod treatment.

Please read the MAYZENT information leaflet included in the package.

While you are taking MAYZENT

While on MAYZENT you must not become pregnant.
You must use effective methods of birth control during treatment and for at least 10 days after you stop treatment.

If you plan to become pregnant, or if you become pregnant, please talk with your doctor as you will need to stop MAYZENT treatment. Your doctor will provide counselling about the potential risks to the foetus that MAYZENT can cause, and discuss the possible return of disease activity upon stopping MAYZENT treatment.

Tell your doctor immediately if you become pregnant while taking MAYZENT because treatment will have to be stopped. Your doctor will discuss the possible return of disease activity with you.
You will also be provided with follow-up medical examinations (e.g. ultrasonography examination).

أثناء تناوُلكِ عقار مايزنت

عليكِ تجنُّب حدوث حَمْل أثناء تناوُل عقار مايزنت.
يجب عليكِ استخدام وسائل فعَّالة لمنع الحَمْل أثناء العلاج ولمدة ١٠ أيام على الأقل بعد إيقافكِ العلاج.

إذا كنتِ تخططين للحَمْل أو اصبحتي حاملاً، فيُرجى التحدُّث مع طبيبكِ؛ إذ ستحتاجين إلى إيقاف العلاج. سيقدم طبيبكِ المشورة بخصوص المخاطر المُحتمَلة لعقار مايزنت على الجنين، كما سيناقش معكِ إمكانية عودة نشاط المرض.

أخبري طبيبكِ فورًا إذا أصبحتِ حاملًا أثناء تناوُلكِ عقار مايزنت سيطلب منكِ طبيبكِ اجراء فحوصات طبية للمتابعة (على سبيل المثال: فحص بالموجات فوق الصوتية).

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أثناء تناوُلكِ عقار مايزنت

إذا حدث حَمْل أثناء العلاج بعقار مايزنت، فيُرجى إبلاغ طبيبكِ أو إبلاغ شركة نوفارتس عن طريق الاتصال بالرقم: ٨١٠٠ ٢٦٥ ٩٦٦١١+ أو
الفاكس: ٨١٠٧ ٢٦٥ ٩٦٦١١+ أو الإيميل: adverse.events@novartis.com
أو عن طريق الموقع الإلكتروني: https://psi.novartis.com/

وضعت شركة نوفارتس برنامج مراقبة مكثفة لنتائج الحَمْل (PRIM) لجمع معلومات حول الحَمْل في المريضات اللاتي تعرَّضن لعقار مايزنت قبل الحَمْل مباشرةً أو أثنائه والنتائج المتعلقة بالرَّضْع بعد ١٢ شهرًا من الولادة.

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While you are taking MAYZENT

Should a pregnancy occur during treatment with MAYZENT, please report it to your doctor or to Novartis Phone: +966 11 265 8100 - Fax: +966 11 265 8107 - Email: adverse.events@novartis.com or visiting the website: https://psi.novartis.com/

Novartis has put in place a Pregnancy outcomes Intensive Monitoring (PRIM) program to collect information about pregnancy in patients exposed to MAYZENT immediately before or during pregnancy and infant outcomes 12 months post delivery

After stopping MAYZENT

Effective methods of birth control should be used for at least 10 days after you stop MAYZENT treatment.

Should a pregnancy occur within 10 days following discontinuation of treatment please report it to your doctor or to Novartis Phone: +966 11 265 8100 - Fax: +966 11 265 8107 - Email: adverse.events@novartis.com or visiting the website: https://psi.novartis.com/

- Novartis has put in place a Pregnancy outcomes Intensive Monitoring (PRIM) program to collect information about pregnancy in patients exposed to MAYZENT immediately before or during pregnancy and infant outcomes 12months post-delivery.

Inform your doctor immediately if you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms after stopping treatment with MAYZENT.

بعد إيقاف العلاج بعقار مايزنت

يجب استخدام وسائل فعَّالة لمنع الحَمْل لمدة ١٠ أيام على الأقل بعد أن تقومي بإيقاف العلاج بعقار مايزنت.

إذا حدث حَمْل في غضون ١٠ أيام بعد إيقاف العلاج، فيُرجى إبلاغ طبيبك أو إبلاغ شركة نوفارتس عن طريق الاتصال بالرقم: ٢٦٥٨١٠٠ ٩٦٦١١+ أو الفاكس: ٢٦٥٨١٠٧ ٩٦٦١١+ أو الإيميل: adverse.events@novartis.com أو عن طريق الموقع الإلكتروني: https://psi.novartis.com/
بصرف النَّظر عن ماهية النتائج العكسية التي جرى رصدها.

• وضعت شركة نوفارتس برنامج مراقبة مكثفة لنتائج الحَمْل (PRIM) لجمع معلومات حول الحَمْل في المريضات اللاتي تعرَّضن لعقار مايزنت قبل الحَمْل مباشرةً أو أثناءه والنتائج المتعلقة بالرُّضَّع بعد ١٢ شهرًا من الولادة.

أبلغي طبيبك فورًا إذا كنت تعتقدين أن مرض التصلُّب المتعدد لديك يتفاقم (على سبيل المثال: ضعفَ أو تغيُّرات بصرية) أو إذا لاحظتِ أي أعراض جديدة بعد إيقاف العلاج بعقار مايزنت.

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بيانات الاتصال الخاصة بطبيبكِ

- [يُضاف هنا اسم الطبيب وبيانات الاتصال الخاصة به]

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Contact details of your doctor

- [Add name and contact details of doctor here]

Mayzent

Important note: Before prescribing, consult full prescribing information. **Presentation:** Tablets: 0.25 mg film-coated tablets corresponding to 0.25 mg siponimod, 2 mg film-coated tablets corresponding to 2 mg siponimod.**Indications: MAYZENT is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease, and active secondary progressive disease, in adults, Dosage and administration:** CYP2C9 genotype should be determined before initiation of treatment. Mayzent should not be used in patients with a CYP2C9*3*3 genotype. Treatment initiation with a starter pack that lasts for 5 days. Once daily intake in the morning. On day 1 and 2: 0.25 mg. On day 3: 0.5 mg. On day 4: 0.75 mg. On day 5: 1.25 mg. Maintenance dose starts on day 6: 2 mg. **Adults:** Maintenance dose: 2 mg once daily. **Special populations:** •Maintenance dose for CYP2C9 *2*3 or *1*3 genotype: 1 mg once daily treatment initiation On day 1 and 2: 0.25 mg, On day 3: 0.5 mg, On day 4: 0.75 mg, Do not use the starter pack for patients who will be titrated to the 1-mg maintenance dosage. •No dose adjustments are needed in patients with renal or hepatic impairment or in geriatric patients (65 years or above). **Contraindications:** With patient who have: •A CYP2C9*3/*3 genotype.•In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III or IV heart failure.**•Presence of Mobitz type II second-degree, third degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker.Warnings and precautions: •Infections:** Before initiating treatment with Mayzent, a recent complete blood count (i.e. within last 6 months or after discontinuation of prior therapy) should be available. In patients with severe active infection, wait for resolution before initiating treatment. Effective diagnostic and therapeutic strategies should be used in patients with symptoms of infection while on therapy and up to 3 to 4 weeks after discontinuation (lowering effects on peripheral lymphocyte count). Consider discontinuing therapy if a serious infection develops, igilance for clinical symptoms of progressive multifocal leukoencephalopathy (PML) or cryptococcal meningitis (CM) is advised and if diagnosed, Mayzent treatment should be suspended. Patients without a healthcare professional confirmed history of varicella or without vaccination against varicella zoster virus (VZV) should be tested for antibodies to VZV prior to treatment initiation. VZV vaccination is recommended in antibody-negative patients and initiation of treatment should be postponed for 1 month to allow the full effect of vaccination to occur. **•Macular edema:** Patients with history of uveitis and patients with diabetes mellitus are particularly at risk of developing macular edema. An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients before starting treatment and at any time if there is any change in vision while taking MAYZENT. Discontinuing therapy should be considered if macular edema develops. **•Treatment initiation:** Should not be used in patients with second-degree Mobitz type II or higher AV block, sick-sinus syndrome or sinoatrial heart block (due to the risk of serious cardiac rhythm disturbances). Should not be used in patients with history of cardiac arrest, cerebrovascular disease, uncontrolled hypertension or severe untreated sleep apnea (since significant bradycardia may be poorly tolerated in these patients). Should not be used in patients with significant QT prolongation (QTc >500 msec). In patients with a history of recurrent syncope or symptomatic bradycardia, use of Mayzent should be based on an overall benefit/risk assessment. If treatment is being considered in patients with the aforementioned risk factors, pre-treatment consultation with a cardiologist is recommended to determine the most appropriate monitoring for treatment initiation. **•Bradyarrhythmia and Atrioventricular Conduction Delays:** Patients with sinus bradycardia (HR <55 bpm), first or second-degree [Mobitz type I] AV block, or a history of myocardial infarction or heart failure: patients should be observed for signs and symptoms of bradycardia for a period of 6 hours after the first dose. An ECG prior to dosing, and at the end of the 6-hour observation period is recommended. Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic drugs.**•Missed dose and re-initiation:** If a dose is missed on one day in the first 6 days of treatment or if 4 or more consecutive daily doses are missed during maintenance therapy, the same initial dose titration and monitoring recommendations should apply. **•Respiratory Effects:** Dose-dependent reductions in absolute forced expiratory volume over 1 second (FEV1) were observed in MAYZENT-treated patients as early as 3 months after treatment initiation. Spirometric evaluation of respiratory function should be performed during therapy with MAYZENT if clinically indicated. **•Liver Injury:** Recent transaminase and bilirubin levels should be available before initiation of treatment with Mayzent. A liver function test is recommended in patients who develop symptoms of hepatic dysfunction during treatment and therapy should be discontinued if significant liver injury is confirmed. **•Increased BloodPressure:** Blood pressure should be monitored during treatment with MAYZENT and managed appropriately. **•Unexpected neurological signs:** Vigilance for any unexpected neurological or psychiatric symptoms/signs of accelerated neurological deterioration (PRES) is warranted. •Pharmacogenomics Patients homozygous for CYP2C9*3 genotype approximately 0.4 to 0.5% of Caucasians and less in others) should not be treated with Mayzent. **•Immune System Effects After Stopping MAYZENT:** other therapies during this interval will result in concomitant exposure to siponimod, initiating treatment with MAYZENT after treatment with alemtuzumab is not recommended. •Patients should be observed for a severe increase in disability upon MAYZENT discontinuation and appropriate treatment should be instituted, as required. After stopping MAYZENT therapy, siponimod remains in the blood for up to 10 days. Starting •The tablets contain lactose.**Pregnancy, lactation, females and males of reproductive potential •Pregnancy:** Not recommended unless benefits outweigh risks. No data in human pregnancy. Embryotoxic, fetotoxic and teratogenic in animals. **Lactation:** Not recommended. No data in human factation. Passes into animal milk. **Females and males of reproductive potential:** Effective contraceptive measures are recommended in women of child-bearing potential during treatment with Mayzent and for at least 10 days after stopping treatment. **Adverse drug reactions: •Headache** (tension headache, sinus headache, cervicogenic headache, drug withdrawal headache, and procedural headache). **•Hypertension** (blood pressure increased, blood pressure systolic increased, essential hypertension, blood pressure diastolic increased). **•Transaminase increased** (alanine aminotransferase increased, gamma-glutamyltransferase increased, hepatic enzyme increased, aspartate aminotransferase increased, blood alkaline phosphatase increased, liver function test increased, hepatic function abnormal, liver function test abnormal, transaminases increased). **•Falls. •Edema peripheral** (edema peripheral, joint swelling, fluid retention, swelling face). **•Bradycardia** (sinus bradycardia, heart rate decreased). •Pain in extremity and limb discomfort. •seizure, •pulmonary function test decreased. •Vascular events (ischemic strokes, pulmonary embolisms, and myocardial infarctions). • **Malignancies** (malignant melanoma in situ and seminoma) •In the Extension Part of phase 3 study 2304, a case of cryptococcal meningitis has been reported,**Interactions: •Anti-neoplastic, immune-modulating or immunosuppressive therapies (including corticosteroids):** Caution is required when used concomitantly with Mayzent and during the weeks following administration. Initiating treatment after alemtuzumab is not recommended unless the benefits clearly outweigh the risks. **•Anti-arrhythmic drugs, QT prolonging drugs, drugs that may decrease heart rate:** At treatment initiation, concomitant use is not recommended with Class Ia (e.g. quinidine, procainamide) and Class III (e.g. amiodarone, sotalol) anti-arrhythmic drugs. QT prolonging drugs with known arrhythmogenic properties, heart rate lowering: calcium channel blockers (e.g. verapamil or diltiazem) or other drugs that may lower heart rate (e.g. ivabradine or digoxin). If treatment is being considered in patients with the aforementioned risk factors, pretreatment consultation with a cardiologist is recommended to determine the most appropriate monitoring for treatment initiation or regarding switching to a non-heart rate lowering drug. **•Beta-blockers:** At treatment initiation, use with caution in patients receiving stable dose of beta-blocker if resting heart rate is ≤50 bpm. In this case, beta-blocker should be interrupted and restarted after up-titration to Mayzent maintenance dose. **•Vaccination:** Concomitant use is not recommended with live attenuated vaccines and for 4 weeks after stopping Mayzent therapy, Other vaccines may be less effective if administered during Mayzent treatment and treatment discontinuation 1 week prior to until 4 weeks after a planned vaccination is recommended. **•CYP2C9 and CYP3A4 inhibitors:** Caution is required with moderate CYP2C9/CYP3A4 inhibitors (e.g. fluconazole) in patients with CYP2C9*2*2 or dosage adjustment to Mayzent 1 mg daily may be considered (approximately 2.74-fold increase of siponimod exposure is expected). **•CYP2C9 and CYP3A4 inducers:** Caution is required with strong CYP3A4/moderate CYP2C9 inducers (e.g. carbamazepine) in all patients and with moderate inducers of CYP3A4 (e.g. modafinil) in patients with CYP2C9*1/3 and*2/3 (a reduction in siponimod exposure is expected). **•Oral Contraceptives:** No interaction studies have been performed with OCs containing other progestogens; however, an effect of siponimod on their exposure is not expected.

Packs and prices: Country-specific.

Legal classification: Country-specific.

Tracking No.: Initial Labelling Package.

Version No. V1.0

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Phone: +966112658100

Fax: +966112658107

Email: adverse.events@novartis.com

Or by online: https://report.novartis.com/

Saudi Food and Drug Authority National Pharmacovigilance Center

Unified Contact Center: 19999

Fax: +966112057662

Email: npc.drug@sfda.gov.sa

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الهاتف: ٠٠٩٦٦١١٢٦٥٨١٠٠

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