دليل المريض:
أشياء مهمة يجب تذكّرها حول عقار جيلينيا (فينجوليمود)

نشرة توعوية للمريض

Gilenya EU RMP V18 Feb 2021
This document is approved by
The Executive Directorate of Pharmacovigilance, at SFDA.

Patient Guide:
Important things to remember about your Gilenya® (fingolimod) treatment

Patient Reminder Card

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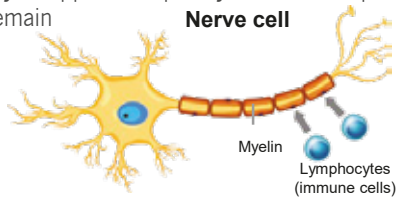
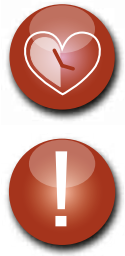
What is multiple sclerosis?

MS is a long-term condition that affects the central nervous system (CNS), comprised of the brain and spinal cord. In MS, inflammation destroys the protective sheath (called myelin) around the nerves in the CNS and stops the nerves from working properly. This is called demyelination.

Relapsing-remitting MS is characterised by repeated attacks (relapses) that reflect inflammation within the CNS. Symptoms vary from patient to patient Symptoms of a relapse may disappear completely when the relapse is over, but some problems may remain





ما هو مرض التصلب المتعدد؟

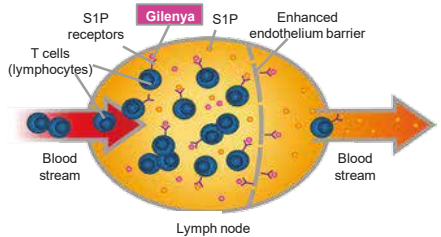
مرض التصلب العصبي المتعدد عبارة عن حالة مرضية تصيب الجهاز العصبي المركزي (الذي يتكون من المخ والنخاع الشوكي)، وهو مرض التهابي مزمن (يُطلق عليه اسم "المرض المُزيل للمَيالين") يؤدي إلى تلف الغطاء الواقي (الغلاف النخاعي) الذي يحيط بالألياف العصبية في الجهاز العصبي المركزي. وعندما يتلف الغلاف النخاعي، تتوقف النبضات العصبية عن العمل بشكل صحيح، مما يؤدي إلى حدوث أمراض عصبية.

يكون مرض التصلّب المتعدد متكرر الانتكاس مصحوبًا بنوبات متكررة تتسبب في حدوث التهاب في الجهاز العصبي المركزي. كما تتفاوت أعراض المرض من مريض لآخر وقد تختفي أعراض الانتكاس بالكامل عند انتهاء الانتكاس، ولكن قد تظل هناك بعض الأعراض الأخرى.

How does Fingolimod work?

It is not fully understood how Gilenya therapy works in MS.

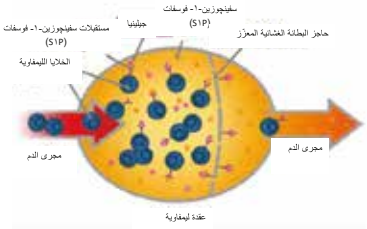
Gilenya helps to protect against attacks on the CNS by the immune system by reducing the ability of some white blood cells (lymphocytes) to move freely within the body and by stopping them from reaching the brain and spinal cord. This limits nerve damage caused by MS. Gilenya also reduces some of the immune reactions of your body.



آلية عمل عقار فينجوليمود؟

ليس هناك فهم كامل لآلية عمل عقار جيلينيا في علاج مرض التصلب العصبي المتعدد.

يساعد عقار جيلينيا على الحماية من النوبات التي تصيب الجهاز العصبي المركزي عبر الجهاز المناعي من خلال الحد من قدرة بعض خلايا الدم البيضاء (الخلايا اللمفاوية) على الانتقال داخل الجسم ومنعها من الوصول إلى الدماغ والحبل الشوكي، وهذا بدوره يحدّ من تلف الأعصاب الناجم عن مرض التصلب العصبي المتعدد. كما يقلّل عقار جيلينيا من بعض التفاعلات المناعية التي تحدث داخل الجسم.



Contraindications and precautions

Gilenya (fingolimod) should not be used in patients with specific cardiac diseases, and is not recommended in patients who are also taking medicines that are known to decrease heart rate.

Gilenya must not be used in women who are pregnant and women of child-bearing potential (including female adolescents) not using effective contraception.

Your doctor will ask you to stay at the surgery or clinic for six or more hours after taking the first dose so that appropriate measures can be taken if side effects occur. In some circumstances, an overnight stay may be required.

Similar precautions will be taken if their dose is increased from 0.25 mg to 0.5 mg once daily.

موانع الاستعمال والاحتياطات

يُمنع استعمال جيلينيا (فينجوليمود) للمرضى المصابين بأنواع معينة من أمراض القلب، ولا يُنصح به للمرضى الذين يتناولون عقاقير تؤدي إلى انخفاض معدل ضربات القلب.

يحظر استعمال جيلينيا للنساء الحوامل والنساء والمراهقات ذوات القدرة على الإنجاب واللائي لا يستخدمن وسائل منع الحمل الفعّالة.

سيوصيك طبيبك بالبقاء في غرفة العمليات أو العيادة لمدة ست ساعات أو أكثر بعد تناول الجرعة الأولى حتى يمكن اتخاذ التدابير المناسبة في حالة حدوث أي آثار جانبية. في بعض الحالات، قد تستدعي الحاجة الإقامة لمدة ليلة واحدة.

سيتم اتخاذ احتياطات مماثلة إذا تم زيادة الجرعة من ٠,٢٥ ملغ إلى ٠,٥ ملغ مرة واحدة يومياً.

Contraindications and precautions

All women of child-bearing potential (including female adolescents) will be provided with a Pregnancy-Specific Patient Reminder Card.

Please read the Patient Information Leaflet thoroughly before starting treatment with Gilenya.

Please inform your doctor if you or a family member have a history of epilepsy.

Contact your doctor immediately if you experience any adverse reactions during treatment with Gilenya or in case of pregnancy.

Please tell any doctor you see that you are taking Gilenya.

موانع الاستعمال والاحتياطات

يجب تزويد جميع النساء والمراهقات ذوات القدرة على الإنجاب ببطاقة تذكيرية خاصة بالحمل.

يُرجى قراءة نشرة معلومات المريض بعناية قبل استخدام عقار جيلينيا.

يُرجى إبلاغ طبيبك إذا كان لديك أو لدى أحد أفراد أسرتك تاريخ مرضي سابق بالصرع.

اتصل بطبيبك على الفور في حال ظهور أي آثار جانبية أثناء استخدام جيلينيا أثناء الحمل.

يُرجى إبلاغ طبيبك بأنك تستخدم جيلينيا.

Before starting Fingolimod treatment

Pregnancy – Gilenya is teratogenic. Women of child-bearing potential (including female adolescents) should be informed by their doctor about Gilenya's serious risks to the fetus, they must have a negative pregnancy test (verified by a healthcare professional), and must take effective contraception before starting treatment with Gilenya.

Human papilloma virus (HPV)-related cancer – Your doctor will assess whether you need to undergo cancer screening (including a Pap test) and if you should receive the HPV vaccine.

Liver function – Gilenya can cause abnormal results in liver function tests. You will need a blood test prior to treatment initiation with Gilenya.

Seizures – Seizures may occur during treatment. Inform your doctor if you or a family member have a history of epilepsy.

الأمور الواجب مراعاتها قبل استخدام فينجوليمود

الحمْل: قد يتسبب عقار جيلينيا في حدوث تشوهات خِلقية بالجنين. لذا ينبغي على الطبيب المعالج إبلاغ النساء والمراهقات ذوات القدرات الإنجابية بالمخاطر الجسيمة التي تهدّد الجنين نتيجة استخدام جيلينيا، كما يجب إجراء فحص حمل سلبي (لدى أخصائي رعاية صحية)، ويجب عليهن تناول وسائل منع الحمل الفعّالة قبل بدء استخدام جيلينيا.

السرطان الناجم عن فيروس الورم الحليمي البشري (HPV): من المقرر أن يقوم طبيبك بتقييم مدى احتياج حالتك إلى الخضوع لفحص السرطان (بما في ذلك اختبار مسحة عُنق الرحم) ومدى الاحتياج إلى استخدام لقاح (تطعيم) فيروس الورم الحليمي البشري.

وظائف الكبد: قد يتسبب جيلينيا في حدوث نتائج غير طبيعية في اختبارات وظائف الكبد، لذا يجب إجراء فحص الدم قبل استخدام جيلينيا.

النوبات: قد تحدث نوبات أثناء العلاج، لذا يُرجى إبلاغ طبيبك إذا كان لديك أو لدى أحد أفراد أسرتك تاريخ مرضي سابق بالصرع.

The first time you take Fingolimod

Slow heart rate and irregular heartbeat
At the beginning of treatment, Gilenya causes the heart rate to slow down. This may make you feel dizzy or lower your blood pressure. If you experience symptoms such as dizziness, nausea, vertigo, or palpitations or feel uncomfortable after taking the first dose of Gilenya, please immediately inform your doctor.

Before you take the first dose, you will have:

- A baseline electrocardiogram (ECG) to assess the action of your heart
- A blood pressure measurement

Pediatric patients will also be weighed and measured, and will undergo a physical development assessment.

المرة الأولى لاستخدام فينجوليمود

تباطؤ معدل ضربات القلب وعدم انتظام ضربات القلب
في بداية العلاج، يؤدي استخدام عقار جيلينيا إلى تباطؤ معدل ضربات القلب، مما يجعل المريض يشعر بالدوار أو انخفاض ضغط الدم. لذا يُرجى إبلاغ الطبيب المعالج على الفور في حالة ظهور أعراض مثل الدوخة والغثيان والدوار أو خفقان القلب أو الشعور بعدم الارتياح بعد تناول الجرعة الأولى من جيلينيا.

يجب إجراء الفحوصات التالية قبل تناول الجرعة الأولى من جيلينيا:

- تخطيط القلب الكهربائي لتقييم نشاط القلب.
- قياس ضغط الدم.

سيتم أيضًا وزن وقياس مرضى الأطفال، وسيخضعون للتقييم البدني.

The first time you take Fingolimod

During the -6hour monitoring, you will have:

- Your pulse and blood pressure checked every hour
  – You may be monitored with a continuous ECG during this time
- An ECG at the end of 6 hours

Call your doctor in case of treatment interruption. If you have stopped Gilenya for 1 day or more during the first 2 weeks of treatment, or for more than 7 days during weeks 3 and 4 of treatment, or if you have stopped Gilenya for more than 2 weeks after you have been on treatment for at least 1 month, the initial effect on your heart rate may occur again. When you restart your Gilenya therapy, your doctor may decide to monitor you with heart rate and blood pressure measurements every hour, to run ECGs, and if needed, to monitor you overnight.

المرة الأولى لاستخدام فينجوليمود

أثناء المتابعة على مدار ٦ ساعات، يجب إجراء ما يلي:

- فحص نبض القلب وضغط الدم كل ساعة.
- متابعة الحالة بإجراء تخطيط القلب الكهربائي باستمرار خلال هذه الفترة.
- تخطيط القلب الكهربائي في نهاية الـ ٦ ساعات.

اتصل بطبيبك في حالة إيقاف العلاج. كما أنه في حال توقفت عن استخدام عقار جيلينيا لمدة يوم واحد أو أكثر خلال أول أسبوعين من العلاج، أو لأكثر من ٧ أيام خلال الأسبوعين الثالث والرابع من العلاج، أو لأكثر من أسبوعين بعد الخضوع للعلاج لمدة شهر واحد على الأقل، قد يحدث الأثر الأولي على معدل ضربات القلب مرة أخرى. وعند معاودة استخدام عقار جيلينيا، قد يوصي طبيبك بمتابعة حالتك من خلال قياس معدل ضربات القلب وضغط الدم كل ساعة أو إجراء تخطيط القلب الكهربائي، وحسب حدّة الحالة، بغية متابعة حالتك ليلًا.

While you are taking Fingolimod

Infections – Because Gilenya affects the immune system, you are more likely to get infections. If you think you have any of the following, during and up to 2 months after stopping treatment, call your doctor straight away: a headache accompanied by a stiff neck, sensitivity to light, fever, flu-like symptoms, nausea, rash, shingles and/or confusion or seizures (fits) (possible symptoms of meningitis and/or encephalitis, either caused by fungal or viral infection).

If you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new symptoms, talk to your doctor as soon as possible. These may be the symptoms of a rare brain disorder called progressive multifocal leukoencephalopathy (PML), which is cased by an infection.

أثناء استخدام عقار فينجوليمود

العدوى: نظرًا لأن عقار جيلينيا يؤثر على الجهاز المناعي، ربما يكون الجسم أكثر عرضة للإصابة بالعدوى. إذا كنت ترى أنك مصابًا بأي مما يلي خلال فترة تصل إلى شهرين بعد توقف العلاج، فاتصل بطبيبك على الفور: الصداع المصحوب بأوجاع فى الرقبة،الحساسية للضوء، اعراض تشبه الانفلونزا، الغثيان ، طفح جلدى، القوباء المنطقية و/أو الأرتباك أو النوبات.
(نوبات) (الأعراض المحتملة لالتهاب السحايا و / أو التهاب الدماغ أيضًا بسبب عدوى فطرية أو فيروسية).

إذا كنت ترى أن مرض التصلب العصبي المتعدد لديك يزداد سوءًا (مثل الشعور بالوهن أو تغيرات في العين) أو إذا لاحظت أي أعراض جديدة، اتصل بطبيبك على الفور. فربما تكون هذه هي أعراض مرض نادر يصيب الدماغ يسمى "اعتلال الدماغ التصاعدي متعدد البؤر (PML)، والتي ينتج عن الإصابة بالعدوى.

While you are taking Fingolimod

Skin cancer – Skin cancers have been reported in multiple sclerosis patients treated with Gilenya. Inform your doctor immediately 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 color, shape or size over time.

Liver function – Some cases of acute liver failure requiring liver transplant and clinically significant liver injury have been reported. The child/adolescent in your care will need a blood test at months 1, 3, 6, 9, and 12 during Gilenya therapy and regularly thereafter until 2 months after Gilenya discontinuation. Inform their doctor immediately if you notice the child/adolescent has yellowing of their skin or the whites of their eyes, abnormally dark urine, pain on the right side of the stomach area, tiredness, feeling less hungry than usual or unexplained nausea and vomiting as these can be signs of liver injury.

أثناء استخدام عقار فينجوليمود

سرطان الجلد - تم الإبلاغ عن الإصابة بسرطان الجلد لدى مرضى التصلب المتعدد الذين تلقوا علاج جيلينيا. أخبر الطبيب على الفور إذا لاحظت أن الطفل/المراهق يعاني أي عقد جلدية (على سبيل المثال, عقد لامعة ولؤلؤية), أو بقع, أو تقرحات مفتوحة لا تلتئم في غضون أسابيع. قد تشمل أعراض سرطان الجلد نمواً غير طبيعي أو تغيرات في أنسجة الجلد (مثل الشامات غير العادية) مع تغير في اللون أو الشكل أو الحجم مع مرور الوقت.

وظيفة الكبد - تم الإبلاغ عن بعض حالات الفشل الكبدي الحاد التي تتطلب زراعة كبد وإصابة كبدية كبيرة سريريًا. سيحتاج الطفل / المراهق الذي تحت رعايتك إلى فحص دم في الأشهر ١ و ٣ و ٦ و ٩ و ١٢ أثناء العلاج بـ جيلينيا وبشكل منتظم بعد ذلك حتى شهرين بعد توقف جيلينيا. أبلغ الطبيب فورًا إذا لاحظت أن الطفل / المراهق يعاني من اصفرار الجلد أو بياض العين، وبول غامق بشكل غير طبيعي، وألم في الجانب الأيمن من منطقة المعدة، والتعب، والشعور بالجوع أقل من المعتاد أو الغثيان والقيء غير المبرر. يمكن أن تكون هذه علامات على إصابة الكبد.

While you are taking Fingolimod

Pregnancy – Women of child-bearing potential (including female adolescents) must have pregnancy tests repeated at suitable intervals during Gilenya treatment.

You should receive regular counseling from a healthcare professional facilitated by the Pregnancy-Specific Patient Reminder Card about the serious risks of Gilenya to the fetus.

You must use effective contraception whilst taking Gilenya, and in the 2 months after you stop taking the treatment because of Gilenya's serious risks to the fetus.

Immediately report to your doctor any (intended or unintended) pregnancy during and for 2 months following discontinuation of treatment with Gilenya.

أثناء استخدام عقار فينجوليمود

الحمل: يجب على النساء والمراهقات ذوات القدرة على الإنجاب إجراء اختبارات حمل متكررة على فترات مناسبة أثناء استخدام جيلينا.

يجب الاستعانة بمشورة طبية منتظمة من أخصائي الرعاية الصحية بالرجوع إلى البطاقة التذكيرية الخاصة بالحمل حول المخاطر الجسيمة التي تهدّد الجنين نتيجة استخدام جيلينيا.

يجب استخدام وسائل منع الحمل الفعّالة أثناء استخدام جيلينيا، وخلال شهرين بعد التوقف عن تناول استخدام جيلينيا نتيجة المخاطر الجسيمة التي تهدّد الجنين نتيجة استخدام جيلينيا.

يجب إبلاغ طبيبك على الفور بحدوث حمل (مقصود أو غير مقصود) خلال شهرين بعد إيقاف جيلينيا.

While you are taking Fingolimod

Visual symptoms – Gilenya may cause swelling at the back of the eye, a condition that is known as macular edema. Tell your doctor about any changes in your vision during and up to 2 months after stopping treatment.

Depression and anxiety – Both conditions have been reported in pediatric patients treated with Gilenya. Talk to your doctor if you are experiencing symptoms.

Stopping Gilenya therapy may result in return of disease activity. Your doctor will decide whether and how you need to be monitored after stopping Gilenya.

أثناء استخدام عقار فينجوليمود

أعراض إصابة العين – قد يتسبب جيلينيا في تورّم الجزء الخلفي من العين، وهي حالة تعرف باسم الوذمة البقعية. لذا يجب إبلاغ طبيبك بأي تغييرات في الرؤية خلال وبعد شهرين من إيقاف العلاج.

الاكتئاب والقلق – تم الإبلاغ عن كلتا الحالتين في مرضى الأطفال الذين تم علاجهم بواسطة دواء جيلينيا. تحدث إلى طبيبك إذا كنت تعاني من الأعراض المذكورة.

قد يؤدي التوقف عن استخدام جيلينيا إلى معاودة نشاط المرض، وسيتخذ الطبيب المعالج قراره بمدى الحاجة إلى متابعة الحالة بعد إيقاف عقار جيلينيا وكيفية المتابعة.

Gilenya®
Important note: Before prescribing, consult full prescribing information. **Presentation:** 0.5 mg hard capsules **Indications:** Gilenya is indicated as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of adult patients and paediatric patients aged 10 years and older:- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (for exceptions and information about washout periods see sections 4.4 and 5.1) or - Patients with rapidly evolving severe multiple sclerosis defined by 2 or more disabling relapses in one year, and with T1 gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI. **Dosage and administration: Adults:** One 0.5 mg capsule taken orally once daily. **Children and adolescents:** Children and adolescents with a body weight ≤ 40 kg: one 0.25 mg capsule per day; with a body weight > 40 kg: one 0.5 mg capsule per day. Not studied in pediatric patients below 10 years of age. The strength 0.25mg supporting the age group between 10 and 18 years old with body weight of 40kg or under is not registered.**Special populations:** No dosage adjustment needed for renal impairment, mild to moderate hepatic impairment or elderly patients (caution as experience is limited). Caution in patients with severe hepatic impairment.**Contraindications:** Patients who in the last 6 months had myocardial infarction, unstable angina pectoris, stroke/transient ischemic attack, decompensated heart failure (requiring inpatient treatment), or New York Heart Association Class III/IV heart failure. •Patients with severe cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs. •Patients with second-degree Mobitz type II atrioventricular (AV) block or third-degree AV block, or sick-sinus syndrome, if they do not have a pacemaker. •Patients with a baseline QTc interval ≥ 500 msec. •Women hypersensitivity to fingolimod, or to any of the excipients. •During pregnancy and in women of childbearing potential not using effective contraception •Hypersensitivity to the active substance or to any of the excipients **Warnings and precautions:** ECG to be performed in all patients prior to the first dose and at the end of the 6-hour first-dose observation period. Heart rate and blood pressure to be monitored hourly during the 6-hour observation period. Same recommendations applies after an interruption of one day or more during the first 2 weeks of treatment, or for more than 7 days during week 3 and 4 of treatment, or after an interruption for more than 2 weeks after the first month of treatment. If post-dose bradyarrhythmia-related symptoms occur, or new onset of second-degree or higher AV block, or the heart rate at 6 hours post-dose is the lowest value post-dose or is <45 bpm in adults, <55 bpm in pediatric patients aged 12 years and above, or <50 bpm in pediatric patients 10 to below 12 years, the patient should be observed until the symptoms or findings have resolved, and appropriate management should be initiated as necessary. Patients should be monitored overnight if ECG at 6 hours shows QTc ≥500 msec. If a patient requires pharmacological intervention during the first dose observation period, overnight monitoring should be instituted and the first dose monitoring strategy should be repeated for the second dose of Gilenya. •When switching pediatric patients from a 0.25 mg to a 0.5 mg daily dose, it is recommended to repeat the first-dose observation period. •Due to the risk of reduction in heart rate, rhythm disturbances, and conduction disturbances at the initiation of treatment, caution should be exercised in patients with significant QT prolongation (QTc >470 msec (adult females), QTc >460 msec (pediatric females) or >450 msec (adult and pediatric males)). Gilenya is best avoided in patients with relevant risk factors for QT prolongation, for example, hypokalemia, hypomagnesemia or congenital QT prolongation. Gilenya should also not be used in patients with history of cardiac arrest, uncontrolled hypertension or severe untreated sleep apnea, since significant bradycardia may not be well tolerated in these patients. If treatment is being considered in patients with the aforementioned risk factors, pre-treatment consultation with a cardiologist is required to determine the most appropriate monitoring (should last overnight) for treatment initiation. •Caution should generally be exercised in patients on concurrent therapy with beta-blockers, heart rate lowering calcium channel blockers or other substances that may decrease heart rate (limited experience is available and this may be associated with severe bradycardia and heart block). If treatment with Gilenya is being considered, advice should be sought from a cardiologist regarding switching to a non-heart rate lowering drug or appropriate monitoring (should last overnight) for treatment initiation. •After the first dose, the heart rate decrease starts within an hour and the Day 1 decline is maximal within 6 hours. Heart rate returns to baseline within 1 month of chronic dosing. •Caution is required in concomitant use with anti-neoplastic, immune-modulating or immunosuppressive therapies (including corticosteroids). Specific decisions as to the dosage and duration of treatment with corticosteroids should be based on clinical judgment. Short courses of corticosteroids can be used in combination with Gilenya. •Patients without a healthcare professional confirmed history of chickenpox 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 vaccination to take full effect. •In pediatric patients, a complete vaccination schedule is recommended before starting Gilenya. •Infection: Lymphocyte count is decreased during Gilenya therapy and up to 2 months after stopping Gilenya therapy. Before initiating treatment with Gilenya, a recent complete blood count (i.e. within 6 months or after discontinuation of prior therapy) should be available. Initiation of treatment with Gilenya should be delayed in patients with severe active infection until resolution. Effective diagnostic and therapeutic strategies should be used in patients with symptoms of infection while on therapy and up to two months after discontinuation. Consider discontinuing therapy if a serious infection develops, and re-evaluate benefit-risk before restarting therapy. Cases of progressive multifocal leukoencephalopathy (PML) have been reported in the post-marketing setting. PML cases without previous treatment with natalizumab have been reported after approximately 2-3 years of treatment although an exact relationship with duration is unknown. The incidence rate for PML appears to be higher for patients in Japan; the reasons are currently unknown. Vigilance for clinical symptoms or MRI findings suggestive of PML is warranted. If PML is suspected, Gilenya treatment should be suspended until PML has been excluded. Cases of cryptococcal meningitis (CM) have been reported in the post-marketing setting with fingolimod and this appears to increase with cumulative exposure over time, an exact relationship with the duration of treatment is unknown. CM may be fatal. For this reason patients with symptoms and signs consistent with CM should undergo prompt diagnostic evaluation. If diagnosed, appropriate treatment should be initiated. •Macular edema: Patients with history of uveitis and patients with diabetes mellitus are particularly at risk of developing macular edema. An ophthalmic examination is recommended 3 to 4 months after Gilenya therapy initiation and also before and regularly during Gilenya therapy in patients at risk. Discontinuing therapy should be considered if macular edema develops. •Recent (i.e. within last 6 months) transaminase and bilirubin levels should be available before initiation of treatment with Gilenya. A liver function test is recommended in patients who develop symptoms of hepatic dysfunction during treatment. Therapy should be discontinued if significant liver injury is confirmed. •Maternal reversible posterior encephalopathy syndrome (PRES): Discontinue Gilenya treatment, if PRES is suspected. •Caution is required when switching patients from natalizumab or teriflunomide to Gilenya due to the long half-life of natalizumab or teriflunomide. Initiating treatment with Gilenya after alemtuzumab is not recommended unless the benefits clearly outweigh the risks. •Basal cell carcinoma (BCC) and other cutaneous neoplasms including malignant melanoma, squamous cell carcinoma, Kaposi's sarcoma and Merkel cell carcinoma, have been reported in patients receiving Gilenya. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Since there is a potential risk of malignant skin growths, patients treated with Gilenya should be cautioned against exposure to sunlight without protection.Vigilance for BCC and other cutaneous neoplasms is warranted. •Cases of hydrocortisone, heterogeneous nature, mainly Non-Hodgkin's Lymphoma, including B-cell and T-cell lymphomas as well as T cell lymphoma (mycosis fungoides) have been reported in clinical studies and/or the post-marketing setting. •Rare cases of tumefactive lesions associated with MS relapse were reported in the post-marketing setting. In case of severe relapses, MRI should be performed to exclude tumefactive lesions. Discontinuation of Gilenya should be considered by the physician on a case-by-case basis taking into account individual benefits and risks. •Cases of severe exacerbation of the disease have been reported after discontinuation of Gilenya. These cases were generally observed within 12 weeks after stopping Gilenya, but in some cases up to and beyond 24 weeks after stopping Gilenya. If treatment is discontinued when stopping Gilenya therapy: patients should be monitored for relevant signs and symptoms and appropriate treatment should be initiated as required. During routine MRI (in accordance with national and local recommendations), vigilance for BCC and other cutaneous neoplasms is warranted. As with other MS medications, detection of JCV DNA in the cerebrospinal fluid and MRI findings may be apparent before clinical signs or symptoms. •The combination of fingolimod with potent CYP450 inducers should be used with caution. Concomitant administration with St John's wort is not recommended. •Gilenya should be used with caution in patients with severe respiratory disease, pulmonary fibrosis and chronic obstructive pulmonary disease. Human papilloma virus (HPV) infection and HPV-related cancer have been reported under treatment with Gilenya in the post-marketing setting. Vaccination against HPV should be considered prior to treatment initiation with Gilenya taking into account vaccination recommendations. Cancer screening, including Pap test, is recommended as per standard of care. **Pregnancy, lactation, females and males of reproductive potential Pregnancy:** While on treatment, females should not become pregnant and effective contraception is recommended. If a female becomes pregnant while taking Gilenya, discontinuation of Gilenya should be considered. Gilenya should not be used during pregnancy unless the clinical need for the individual patient justifies potential risks identified for both the mother and the fetus. **Lactation:** Breast feeding is not recommended. **Females and males of reproductive potential** should be verified prior to starting treatment and Adequate effective contraceptive measures are recommended in women of childbearing potential during treatment with Gilenya and for 2 months after stopping treatment. **Adverse reactions:** Frequencies were defined using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data). **Very common (≥10%):** Influenza, sinusitis, headache, cough, diarrhoea, back pain, hepatic enzymes increased. **Common (≥1 to <10%):** Herpes viral infections, Bronchitis/sinus sensation, Cancer, Lymphopenia, leucopenia, Depression, dizziness, migraine, vision blurred, bradycardia, Atrioventricular block, hypertension, dyspnea, eczema, alopecia, pruritus, Myalgia, Arthralgia, asthenia, Weight decreased, blood triglycerides increased. **Uncommon (≥0.1 to <1%):** Pneumonia, Malignant melanoma, Thrombocytopenia, Depressed mood, macular edema, Nausea, Neutrophil count decreased, seizures, including status epilepticus (in the pediatric study, cases of seizures were reported in 5.6% of fingolimod-treated patients and 0.9% of interferon beta-1a treated patients), **Rare (≥0.01 to <0.1%):** Lymphoma, Posterior reversible encephalopathy syndrome (PRES). **Very rare (<0.01%):** Kaposi's sarcoma, Hearing impairment, **Not known:** Progressive multifocal leukoencephalopathy (PML), Cryptococcal infections (including cryptococcal meningitis), Merkel cell carcinoma, Autoimmune haemolytic anaemia, Peripheral oedema, Hypersensitivity reactions, including rash, urticaria and angioedema upon treatment initiation, Severe exacerbation of disease after Gilenya discontinuation. Cases of infections with opportunistic pathogens, such as viral (e.g. VZV, JCV causing PML, HSV), fungal (e.g. cryptococcus including cryptococcal meningitis) or bacterial (e.g. atypical mycobacterium), have been reported in the post-marketing setting. Isolated cases of transient spontaneously resolving complete AV block have been observed during the six hour observation period. **Interactions:** •Concomitant use is not recommended with Class Ia (e.g. quinidine, procainamide) and Class III (e.g. amiodarone, sotalol) anti-arrhythmic drugs •Antihypertensive medication concomitant use with beta-blockers, heart rate lowering calcium channel blockers (e.g. verapamil or diltiazem) or other drugs that may lower heart rate (e.g. ivabradine or digoxin) is not recommended. •Caution is required in concomitant use with anti-neoplastic, immune-modulating or immunosuppressive therapies (including corticosteroids) during, and for up to 2 months after stopping Gilenya treatment. •Caution is required when switching therapy from drugs with a long-acting immune effect such as natalizumab, teriflunomide or mitoxantrone. •Concomitant use of vaccines with live attenuated vaccines, other vaccines may have reduced efficiency during and for up to 2 months after stopping Gilenya therapy. • caution should be done with substance that inhibit CYP3A4.
Packs and prices: Country specific.
Legal classification: Country specific.
Tracking No.: SA_v2.0_NSS_Gilenya_17Nov20

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Patient Safety Department Novartis Pharma AG - Saudi Arabia -.
Toll Free Number: 8001240078
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Or by online: http://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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الايميل: adverse.events@novartis.com
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