جيلينيا (فينجوليمود)
البطاقة التذكيرية الخاصة بالحمل

نشرة توعوية للمريض

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

Gilenya® (fingolimod): Pregnancy-Specific Patient Reminder Card

Patient Reminder Card

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Before starting Fingolimod treatment

Gilenya (fingolimod) is contraindicated in pregnant women and women of child-bearing potential (including female adolescents) not using effective contraception.

At treatment start and then regularly, your doctor will inform you about the teratogenic risk and required actions to minimize this risk.

A pregnancy test must be conducted and the negative result verified by a doctor before starting treatment.

Your doctor will inform you about the need for effective contraception while on treatment and for 2 months after discontinuation. Talk to your doctor about the most effective contraception options available to you.

Please read the Gilenya Patient Guide Leaflet provided by your doctor.

الأمور الواجب توافرها قبل استخدام عقار فينجوليمود

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

أثناء العلاج وبعده بصورة منتظمة، سيبلغك طبيبك باحتمال حدوث تشوهات بالجنين والإجراءات اللازمة لتقليل هذا الاحتمال.

قبل بدء العلاج، يجب إجراء اختبار الحمل والتحقق من النتيجة السلبية من خلال أخصائي.

سيقوم طبيبك بإبلاغك بالحاجة إلى استخدام وسائل منع الحمل الفعّالة أثناء العلاج ولمدة شهرين بعد إيقافه. تحدّث إلى طبيبك حول وسائل منع الحمل المتاحة الأكثر فعالية.

يُرجى قراءة كتيب دليل المريض لعقار جيلينيا الذي يقدّمه إليك طبيبُك.

While you are taking Fingolimod

While on treatment women must not become pregnant.

Patients must use effective contraception while taking Gilenya.

Women must not become pregnant during treatment and for 2 months after discontinuing treatment.

Pregnancy tests must be repeated at suitable intervals

Your doctor will provide regular counselling about Gilenya's serious risks to the fetus.

If you become pregnant or if you want to become pregnant please discuss this with your doctor because Gilenya treatment must be discontinued.

أثناء استخدام عقار فينجوليمود

يحظر استخدام العقار أثناء الحمل.

يجب على المريضات استخدام وسائل منع الحمل الفعّالة أثناء تناول جيلينيا.

يحظر الحمل اثناء استخدام العقار ولمدة شهرين بعد استخدام العلاج.

ينبغي تكرار اختبارات الحمل على فترات زمنية مناسبة.

سيسدي إليكِ طبيبك مشورات طبية منتظمة حول احتمال تسبب جيلينيا في تشوه الجنين.

إذا كنت حاملاً أو إذا كنت تعتزمين ذلك، يُرجى مناقشة هذا الأمر مع طبيبك لأنه في هذه الحالة يجب التوقف عن تناول جيلينيا.

While you are taking Fingolimod

In the event of a pregnancy your doctor will provide counselling.

Your doctor will give you medical advice regarding the harmful effects of Gilenya to the fetus and will provide an evaluation of the potential outcome.

An ultrasonography examination should be performed, and Gilenya treatment will be discontinued

Your doctor will encourage you to enroll in the Gilenya Pregnancy Registry: https://www.gilenyapregnancyregistry.com/

The purpose of this registry is to monitor the outcomes of pregnancy in women exposed to Gilenya during pregnancy.

أثناء استخدام عقار فينجوليمود

سيسدي إليك طبيبك المشورة الطبية اللازمة أثناء الحمل.

سيسدي إليك طبيبك المشورة الطبية اللازمة حول الآثار الضارة لعقار جيلينيا في الجنين وسيجري تقييماً للنتائج المحتملة.

يجب إجراء فحص بالموجات فوق الصوتية، وأثناء هذه الفترة، يجب التوقف عن تناول جيلينيا.

سيشجعك طبيبك على التسجيل في سجل جيلينيا للحمل: https://www.gilenyapregnancyregistry.com/،

يكمن الغرض من هذا السجل في رصد نتائج الحمل لدى النساء اللائي يستخدمن عقار جيلينيا أثناء الحمل.

After stopping Fingolimod treatment

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 Gilenya due to pregnancy.

Effective contraception is needed for 2 months after stopping Gilenya treatment because of the length of time it takes for Gilenya to leave the body.

بعد إيقاف استخدام فينجوليمود

إذا كنت تعتقد أن مرض التصلب العصبي المتعدد لديك يزداد سوءًا (مثل الشعور بالوهن أو تغيرات في العين) أو إذا لاحظت أي أعراض جديدة بعد التوقف عن تناول عقار جيلينيا بسبب الحمل، اتصل بطبيبك على الفور.

يتعين استخدام وسائل منع الحمل الفعّالة لمدة شهرين بعد إيقاف عقار جيلينيا بسبب طول الوقت الذي يستغرقه عقار جيلينيا في مغادرة الجسم.

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 relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more 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. ♦Known 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 recommendation 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 <60 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 serious cardiac rhythm disturbances, Gilenya should not be used in patients with sino-atrial heart block, a history of symptomatic bradycardia or recurrent syncope or 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. ♦Gilenya should generally not be initiated 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 the duration of treatment 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 after approximately 2 3 years of treatment. Although the estimated risk 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. ♦Posterior reversible 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 protectionVigilance for BCC and other cutaneous neoplasms is warranted. ♦Cases of lymphoma, heterogeneous in 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 Gilenya discontinuation. Caution is indicated 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, taking into account the individual benefit risk assessment for both the mother and the fetus. **Lactation:** Not recommended. **Females and males of reproductive potential:** The pregnancy status of females 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, Bronchitistinea versicolor, basal cell carcinoma, 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, T-wave inversion. **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. cryptococci 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 ♦At treatment initiation 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 is not recommended 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.

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Patient Safety Department Novartis Pharma AG - Saudi Arabia -.

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الهاتف: ٠٠٩٦٦١١٢٦٥٨١٠٠
الفاكس: ٠٠٩٦٦١١٢٦٥٨١٠٧
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الفاكس: ٠٠٩٦٦١١٢٠٥٧٦٦٢
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