Once-daily
GILENYA®
(fingolimod)

HCP INFORMATION

Support for patient initiation from the word go

MS Go

Welcome to MSGo

A digital platform designed to make treatment initiation with GILENYA easier for you and your patients.

ms-go.com.au
Access on all your devices

A range of practical features including:

Pre-screening monitoring

Generate referrals and monitor progress of your GILENYA patients' pre-screening tests.

MSGo nurse support

The MSGo nurse is available to assist you with the GILENYA onboarding process, as well as offering support to your patients.

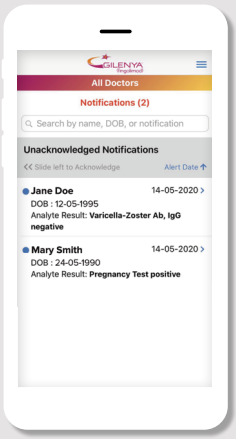
Register for MSGo today at medhub.com.au/msgo or contact your Novartis representative if you have any questions

Contact: _____

Phone: _____ Email: _____

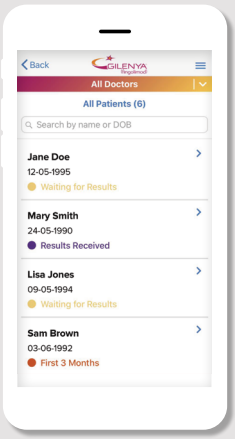
Result notifications

Receive notifications when pre-screening results are ready for review.



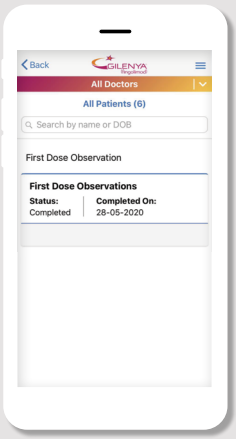
Patient monitoring and collaboration tools

Monitor progress of GILENYA onboarding and share with team members.



First dose observation co-ordination

The MSGo nurse can organise an appointment at any one of the Novartis affiliated first dose observation clinics.



MSGo streamlining GILENYA initiation for you and your patients

01

Enter your patient's details

on the MSGo portal to enrol them in the program

02

Request any required pre-screening tests

and print referrals directly from the MSGo portal

03

Receive notifications

when pre-screening results are ready for review

PBS Information: Authority Required (STREAMLINED).
For use in patients with relapsing-remitting multiple sclerosis who meet certain criteria. Refer to PBS Schedule for full Authority Required information.

See approved Product Information before prescribing.
For the most up to date Product Information go to
www.novartis.com.au/products/healthcare-professionals

GILENYA® (fingolimod) Indication: *Treatment of adult and pediatric patients of 10 years of age and above with relapsing forms of Multiple Sclerosis to reduce the frequency of relapses and delay the progression of disability.* **Dosage and administration:** To be taken orally with or without food. **Adults:** One 0.5 mg capsule taken once daily. ***Children and Adolescents****: body weight ≤ 40 kg: one 0.25 mg capsule per day; weight > 40 kg: one 0.5 mg capsule per day.* Special patient population: 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 and diabetes mellitus. **Contraindications:** Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure. History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick-sinus syndrome, unless patient has a functioning pacemaker. Baseline QTc interval ≥ 500 msec. Concomitant treatment with Class Ia or Class III anti-arrhythmic drugs during Gilenya initiation. Known hypersensitivity to fingolimod or any of the excipients. **Precautions: First dose monitoring:** ECG to be performed, heart rate, blood pressure to be monitored, same recommendation applies after interruption of treatment. **Bradyarrhythmia:** 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, significant QT prolongation, (QTc >470 msec (adult females), *QTc >460 msec (pediatric females),* or >450 msec (adult *and pediatric* males)) relevant risk factors for QT prolongation, concurrent therapy with QT prolonging drugs with a known risk of torsades de pointes. Gilenya should also not be used in patients with history of cardiac arrest, uncontrolled hypertension or severe untreated sleep apnoea since significant bradycardia may not be well tolerated in these patients; Concurrent therapy with beta-blockers, heart rate lowering calcium channel blockers or other substances that may decrease heart rate. **Vaccination** may be less effective during and for up to two months after treatment with Gilenya. The use of live attenuated vaccines should be avoided. Varicella zoster virus (VZV) vaccination is recommended in antibody-negative patients. *In pediatric patients, a complete vaccination schedule is recommended before starting Gilenya.* **Infections:** Lymphocyte count is decreased during Gilenya therapy and up to two months after stopping Gilenya therapy. Do not start Gilenya in patients with active acute or chronic infections until this has resolved. Consider discontinuing therapy if a serious infection develops, and re-evaluate benefit-risk before restarting. Cases of progressive multifocal leukoencephalopathy (PML), cryptococcal meningitis, *human papilloma virus (HPV) infection and HPV-related cancer* have been reported in the post-marketing setting. *Vaccination against HPV should be considered.* **Macular oedema:** Patients with history of uveitis and diabetes mellitus are particularly at risk of developing macular oedema. An ophthalmic examination is recommended before Gilenya therapy initiation and regularly during Gilenya therapy in patients at risk. Discontinuing therapy should be considered if macular oedema develops. **Liver Function:** Recent transaminase and bilirubin levels should be available before initiation of treatment. A liver function test is recommended in patients who develop symptoms of hepatic dysfunction during treatment or with a history of significant liver disease. Gilenya should be discontinued if significant liver injury is confirmed. **Posterior reversible encephalopathy syndrome (PRES):** Discontinue Gilenya treatment if PRES is suspected. **Immunosuppressive or immune-modulating therapies:** Caution when switching patients from natalizumab or teriflunomide to Gilenya. Initiating treatment with Gilenya after alemtuzumab is not recommended unless the benefits clearly outweigh the risks. **Skin cancers:** Basal cell carcinoma (BCC) *and other cutaneous neoplasms* are associated with use of Gilenya. Healthcare professionals and patients are advised to monitor for suspicious skin lesions. ***Lymphoma:*** *mainly Non-Hodgkin's Lymphoma.* ***Tumefactive lesions:*** *associated with MS relapse, MRI recommended in severe cases and consider discontinuation of Gilenya.* ***Return of disease activity:*** *severe exacerbation of disease has been reported after discontinuation of Gilenya, usually within 12 weeks, but in some cases up to and beyond 24 weeks. Patients should be monitored for relevant signs and symptoms, initiate appropriate treatment as required.* ***Pregnancy, fetal risk and contraception:*** *verify pregnancy status before starting treatment. While on treatment and for at least 2 months following discontinuation, females should not become pregnant and effective contraception is recommended. (See full PI for details.)* **Pregnancy:** Category D. *If a female becomes pregnant while taking Gilenya, discontinuation of Gilenya should be considered.* **Breast-feeding:** Women receiving Gilenya should not breast feed. **Interactions:** At treatment initiation concomitant use with beta-blockers, heart rate lowering calcium channel blockers (e.g. verapamil, diltiazem) or other drugs that may lower heart rate (e.g. ivabradine or digoxin) is not recommended. Caution is required in concomitant use of anti-neoplastic, immunosuppressive or immune modulating therapies (including corticosteroids) during and for up to two 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 efficacy during and for up to two months after stopping Gilenya therapy. Patients who use Gilenya and systemic ketoconazole concomitantly should be closely monitored. **Adverse effects:** Very common (>10%): Influenza, sinusitis, headache, diarrhoea, back pain, hepatic enzymes increased, cough. Common (1 to 10%): Bronchitis, herpes zoster, tinea versicolour, basal cell carcinoma, bradycardia, dizziness, migraine, asthenia, eczema, pruritus, hepatic enzyme increased, blood triglycerides increased, liver function test abnormal, dyspnoea, vision blurred, hypertension, leucopenia, lymphopenia. Uncommon (<0.1 to 1%): Pneumonia, macular oedema, *melanoma,* seizures including status epilepticus. Rare (0.01 to 0.1%): Posterior reversible encephalopathy syndrome. *Very rare (<0.01%): Kaposi's sarcoma.* Frequency not known: Hypersensitivity reactions, including rash, urticaria and angioedema upon treatment initiation. *Severe exacerbation of disease after Gilenya discontinuation.* Nausea. Myalgia, arthralgia, *weight decreased.* Thrombocytopenia. Post-marketing setting: Cases of opportunistic infections, some of which were serious, (viral infections such as PML, encephalitis and meningitis (herpes simplex and varicella zoster), fungal infections including cryptococcal meningitis and atypical mycobacterial skin and lung infections), *HPV infection, including papilloma, dysplasia, warts and HPV-related cancer.* Isolated cases of transient spontaneously resolving complete AV block during the six hour observation period. (gil181219m.doc based on gil181219i). ***Please note changes in Product Information in italics.***

Reference: 1. GILENYA TGA-approved Product Information, 18 December 2019.

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