

Dear Doctor,

Your patient has been prescribed fingolimod (Gilenya®) tablets 0.5mg daily for relapsing-remitting multiple sclerosis.

Fingolimod is a sphingosine-1-phosphate receptor modulator that prevents lymphocytes from crossing the blood–brain barrier and causing damage to nerve cells in the brain and spinal cord. Fingolimod is recommended by NICE (Technology Appraisal 254) as an option for the treatment of highly active relapsing–remitting multiple sclerosis in adults who have an unchanged or increased relapse rate or ongoing severe relapses compared with the previous year despite treatment with beta interferon

A brief glance summary of the significant clinical and monitoring issues associated with this drug is enclosed overleaf. The summary of product characteristics and/or BNF should be consulted for further information. Specialist advice regarding drug interactions can be provided by the neurosciences pharmacist (0114 2713225 – phone not continually manned) or our medicines information service (0114 2712346). GPs are encouraged to add this as a hospital issued drug in order to pick up potential interactions. There is a useful reminder on how to do this for GP practices on the [intranet](#).

Written information on how to take the tablets has been provided and counselling given at the hospital. Bradycardia, particularly following administration of the first dose, is a significant risk with fingolimod. The patient has already initiated treatment by attending our neurology day unit and significant bradycardia was not observed, following observation after administration of the first dose.

Fingolimod is funded by the PCT/SCG and is prescribed by the multiple sclerosis service within the neurology department. The medication is delivered to the patient via a homecare delivery company. Hence you will not be able to give prescriptions for this medicine. Their usual repeat medicines should continue as usual. We will write to you again if treatment with fingolimod is stopped so that this can be removed from the patient's record and we will also inform you of any other medication changes by letter.

If you have any queries regarding this or any aspect of their treatment, please do not hesitate to contact.....

Yours faithfully

Brief glance summary of prescribing and monitoring issues for fingolimod (Gilenya®)

Please refer to the BNF and summary of product characteristics for full details

Issue	Notes and monitoring	Monitoring responsibility
Bradycardia	Exclusion of contra-indicated cardiac co-morbidities and first-dose monitoring as outlined in the summary of product of characteristics	Neurology (STH)
	The following drugs are contra-indicated in combination: Class I anti-arrhythmics e.g. quinidine, disopyramide Class III anti-arrhythmics e.g. amiodarone, sotalol Beta-blockers Diltiazem, verapamil, ivabradine Drugs with negative chronotropic effects: Digoxin, pilocarpine, cholinesterase inhibitors (pyridostigmine, neostigmine)	Neurology and primary care Primary care to discuss with neurology if contra-indicated drug deemed necessary.
Infection	Lymphopenia reported - baseline FBC monitoring and then again at months 1, 3, 6, 9, and 12; discontinue fingolimod if lymphocyte count $<0.2 \times 10^9/L$ Patient to be tested for varicella zoster antibodies if history of chicken pox unclear; if antibody negative to be offered VZ vaccine.	Neurology (STH) Primary care to be aware and liaise with neurology if necessary
Macular oedema	Reported in 0.4% patients – previous uveitis and diabetes mellitus are risk factors for development. High risk patients offered baseline testing and all patients offered testing within 4 months of commencing treatment.	Neurology (STH)
	All patients referred immediately for visual testing if visual disturbance reported.	Neurology and primary care
Liver toxicity	Elevated transaminases reported - baseline LFT monitoring and then again at months 1, 3, 6, 9, and 12; Patient retested if transaminases $>5x$ upper limit of normal (ULN) or symptoms suggestive of liver failure (abdominal pain, nausea, vomiting, dark urine, jaundice etc.). Discontinue if transaminases confirmed $>5xULN$.	Neurology (STH) Primary care to be aware and liaise with neurology if necessary
Pharmacokinetic drug interactions	Fingolimod is a substrate for CYP3A4; avoid concomitant macrolide antibiotics e.g. clarithromycin, azole anti-fungals e.g. fluconazole, and certain anti-retroviral agents.	Neurology and primary care