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Direct Healthcare Professional Communication
Fingolimod (▼Gilenya) – contraindications in patients with cardiac conditions

Dear Healthcare Professional,

In agreement with European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA), Novartis would like to inform you of the following:

Summary

Warnings against the use of fingolimod (Gilenya) in patients with underlying cardiac disorders have been strengthened; fingolimod is now contraindicated in:

- **Patients with myocardial infarction, unstable angina pectoris, stroke, transient ischaemic attacks, decompensated heart failure (requiring inpatient treatment), or New York Heart Association (NYHA) class III/IV heart failure in the previous 6 months.**
- **Patients with severe cardiac arrhythmias requiring treatment with class Ia (e.g. quinidine, procainamide, disopyramide) and class III (potassium-channel blockers, e.g. amiodarone, sotalol, ibutilide, dofetilide) 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 wear a pacemaker.**
- **Patients with a baseline QTc interval ≥500 milliseconds.**

Background

Fingolimod is a sphingosine 1-phosphate receptor modulator approved as a single disease-modifying therapy in highly active relapsing-remitting multiple sclerosis for adult patients with:

- highly active disease despite a full and adequate course of treatment with at least one disease-modifying therapy
- 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.

The risk of serious cardiac rhythm disturbances with fingolimod, including polymorphic ventricular arrhythmia (PVA), is already described in the product information. However, cases of PVA, including fatalities have been reported. Therefore, to minimise the risk of severe adverse events in patients with cardiac conditions, contraindications are being introduced. The warnings and precautions on the immunosuppressive effect of fingolimod potentially leading to serious infections and cancer are also being updated.

For complete information on the side effects and risks with fingolimod and the related recommendations for use, please consult the product information (summary of product characteristics (SmPC) and package leaflet).

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Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report

- all suspected ADRs that are serious or result in harm. (Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.)
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form from the Yellow Card section of the MHRA website

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the patient safety information (PSI) tool at https://psi.novartis.com.

Gilenya is subject to additional monitoring to allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Company contact point

If you have any questions or require further information, please contact Novartis Medical Information department on 01276 698370 or email medinfo.uk@novartis.com.

Yours faithfully,

Dr Dimitrios Georgiopoulos, MD
Chief Scientific Officer, Novartis Pharmaceuticals UK Ltd