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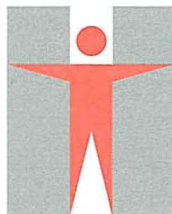
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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,



DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG REGISTRATION AND  
IMPORT/EXPORT CONTROL DIVISION  
3/F., Public Health Laboratory Centre,  
382 Nam Cheong Street, Kowloon, Hong Kong

15 December 2017

**Fingolimod (Gilenya ▼): new contraindications in relation to cardiac risk**

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that Fingolimod can cause transient bradycardia and second-degree or third-degree atrioventricular (AV) block in early treatment.

In Jan 2013, MHRA highlighted the need for cardiac monitoring after the first dose of fingolimod. However, some patients can have persistent bradycardia, which can increase the risk of serious cardiac arrhythmias. A recent routine EU review identified 44 post-marketing reports of serious ventricular tachyarrhythmia and 6 reports of sudden death worldwide in patients taking fingolimod up to the end of Feb 2017. To this date, cumulative exposure to fingolimod post-marketing was estimated to be 397,764 patient-years. The routine EU review recommended that warnings against the use of fingolimod in patients with underlying cardiac disorders should be strengthened to contraindications.

Healthcare professionals are advised that:

- fingolimod can cause serious ventricular arrhythmias, particularly in the first year of use
- fingolimod is now contraindicated in patients with myocardial infarction or unstable angina, cerebrovascular disease (transient ischaemic attacks, stroke), decompensated heart failure (requiring inpatient treatment) or New York Heart Association (NYHA) class III/IV heart failure in the previous 6 months, 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) antiarrhythmic drugs, second-degree Mobitz type II atrioventricular (AV) block or third-degree AV block, or sick-sinus syndrome, if they do not have a pacemaker, pre-treatment QT intervals  $\geq 500$  milliseconds.
- report all suspected adverse drug reactions with fingolimod on a Yellow Card

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/fingolimod-gilenya-new-contraindications-in-relation-to-cardiac-risk>

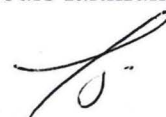
*We build a healthy Hong Kong and  
aspire to be an internationally renowned public health authority*

In Hong Kong, Gilenya Hard Capsules 0.5mg (HK-61192) is a pharmaceutical product containing fingolimod which is registered by Novartis Pharmaceuticals (HK) Limited, and is a prescription-only medicine. So far, the Department of Health (DH) has received one case of adverse drug reaction related to fingolimod, which is related to bradycardia.

Related news was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 21 Dec 2011, with the latest update posted on 24 Aug 2012. Letters to local healthcare professionals to draw their attention about cardiac risk was issued on 23 Apr 2012. In light of the new contraindications in the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: [adr@dh.gov.hk](mailto:adr@dh.gov.hk)). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Joseph LEE)

for Assistant Director (Drug)