

衛生署藥物辦公室  
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓



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

電話號碼 Tel. No.: 2319 8458  
詢問處 Enquiries (852) 2319 8458  
傳真號碼 Faxline No. (852) 2803 4962  
本署檔號 OUR REF.: DH DO PRIE/7-30/15

2 October 2015

(來函請註明此檔案號碼)  
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

**Multiple sclerosis drug Gilenya (fingolimod): risk of skin cancer and a rare brain infection**

Your attention is drawn to the Health Canada's announcement regarding the risk of skin cancer, as well as a rare brain infection known as progressive multifocal leukoencephalopathy (PML) in patients using Gilenya (fingolimod).

Gilenya works by modifying the body's immune system and reducing the access of lymphocytes to the brain and spinal cord, which may reduce the damage that happens in these areas in multiple sclerosis (MS) and the frequency of MS relapses. A Health Canada safety review found that Gilenya, like other drugs that suppress the immune system, may increase the risk of lymphomas (lymphocyte cancer) and other cancers, particularly of the skin.

Medicines that suppress the immune system are also known to reduce the body's ability to fight infections. Cases of PML, a rare infection caused by the John Cunningham (JC) virus, have been reported with Gilenya use - including in patients who were not currently taking and had not previously taken other medications that suppress or change the immune system. The JC virus is a common virus that is harmless in most people but can cause PML in some patients who have weakened immune systems. In severe cases, it can lead to disability or death.

Gilenya labelling in Canada already contained information on the possible risk of lymphoma, and warnings about how this drug reduces the body's ability to fight infection. It has been updated to include the risk of skin cancer and PML specifically, and to advise that patients and health professionals be vigilant for symptoms.

Additional information for healthcare professionals:

- Physicians should be vigilant for skin cancer.
- Physicians should be vigilant for clinical symptoms or MRI findings that may be suggestive of PML. MRI signs of PML may be apparent before clinical symptoms develop.
- If PML is suspected, suspend Gilenya treatment until PML has been ruled out.

Please refer to the Health Canada's website for details:

<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/55160a-eng.php>

In Hong Kong, Gilenya Hard Capsules 0.5mg (HK-61192) is a pharmaceutical product registered by Novartis Pharmaceuticals (HK) Ltd (Novartis), and is a prescription-only medicine. Related news on risk of PML has been released by the US FDA, and was posted on the Drug office website on 30 August 2013 and 5 August 2015. Letters to inform local healthcare professionals of the risk of PML were issued on 5 August 2015. So far, the Department of Health (DH) has not received any adverse drug reaction case on fingolimod.

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

Novartis has applied to the DH to update the package insert of the product to include the relevant warning of PML and basal cell carcinoma (a kind of skin cancer), and the application is under evaluation. As previously reported, the matter concerning PML will be discussed by the Registration Committee of the Pharmacy and Poisons Board (the Committee).

In view of the Health Canada's announcement on the risk of lymphomas (lymphocyte cancer) and other cancers, particularly of the skin, in addition to PML mentioned by the US FDA, the information will also be forwarded to the Committee for consideration. 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,



(Lilly HO)

for Assistant Director (Drug)