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Our ref :

Date : 10/05/2015

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التاريخ :

# Fingolimod (Gilenya): first reported case of progressive multifocal leukoencephalopathy (PML) in a multiple sclerosis patient taking Fingolimod with-out previous treatment by natalizumab or other immunosuppressive medicines

Dear Healthcare Professional,

In agreement with Saudi Food Drug Authority, Novartis would like to inform you of a first case report of PML in a patient taking fingolimod for multiple sclerosis with-out previous treatment by Natalizumab or other immunosuppressive medicines

## Summary

- **A case of PML was reported in February 2015 in a patient who had been taking fingolimod for more than 4 years.**
- **This is the first case report of PML in a multiple sclerosis patient taking fingolimod who had not previously received Natalizumab or other immunosuppressive medicines.**
- **PML was suspected on a routine brain MRI scan and confirmed by positive JC virus DNA in cerebrospinal fluid (CSF) using quantitative PCR. Fingolimod was stopped immediately and to date, the patient has not experienced any clinical signs or symptoms related to PML.**
- **Prescribers are recommended to be vigilant for the risk of PML in patients treated with fingolimod. The treatment should be permanently discontinued in case of PML.**

## Further information

*Case details*

This is the first case report receive of PML in a multiple sclerosis patient taking fingolimod who had not received Natalizumab or other immunosuppressive medicines. A 49 year old patient with multiple sclerosis developed PML while taking fingolimod in February 2015. The patient had received interferon-beta for 10 months until September 2010. Fingolimod 0.5 mg/day was started in October 2010. Between October 2010 and May 2014, the patient had lymphocyte counts between 0.59 and 0.89 x $10^9$/L. On 9 December 2014, the absolute lymphocyte count was 0.24 x $10^9$/L.


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| الرياض | جدة | الدمام |
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| الرياض : ١١٤٦٤ | جدة : ٢١٤٩٢ | الدمام : ٣١٤٥٢ |
| تلفون : ٨٨٨٢ ٤٦٥ | تلفون : ٥٦٦٦ ٦٦٩ | تلفون : ٨٣١٧٤ ٨٣٤ |
| تليفاكس : ٨١٢٧ ٤٦٤ | تليفاكس : ٣٥٣٤ ٦٦٣ | تليفاكس : ٤٢٠٠ ٨٣٤ |

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On 23 January 2015, the patient had a routine magnetic resonance imaging (MRI) scan. Lesions compatible with PML were detected. The patient stopped taking fingolimod on 26 January 2015. The diagnosis was confirmed by a CSF sample which was positive for JC virus in a quantitative polymerase chain reaction (PCR) test. Of note, the patient did not experience

any clinical signs or symptoms of PML. On 5 February 2015, absolute lymphocyte counts were 0.64 x $10^9$/L.

PML is a rare and serious brain disease caused by reactivation of the JC virus. This virus is commonly found in the general population but only leads to PML if the immune system has been weakened. PML can present with similar features to multiple sclerosis as both are demyelinating diseases.

*Indication*
Fingolimod (Gilenya) is a sphingosine 1-phosphate receptor modulator indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Novartis is working with regulatory authorities to evaluate the evidence for the risk of PML and consider if further guidance on managing the risk of PML is needed. Any new advice will be communicated promptly.

## Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):

By email: npc.drug@sfda.gov.sa
Or by fax: +966 11 2057662
Or by online: https://ade.sfda.gov.sa/

Or

Pharmacovigilance department in Novartis:
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com

Riyadh Al Malahi
DS&E Responsible
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| تليفاكس : ٨١٢٧ ٤٦٤ | تليفاكس : ٣٥٣٤ ٦٦٣ | تليفاكس :٤٢٠٠ ٨٣٤ |