New recommendations to minimise risks of the rare brain infection PML and a type of skin cancer with Gilenya

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Information on Medicinal Product

- Gilenya (fingolimod) is a medicine used to treat adults with relapsing-remitting multiple sclerosis.
- Gilenya is reserved for when the disease has failed to respond to at least one other 'disease modifying' agent, or if the disease is severe and getting worse rapidly.
- Gilenya has been authorised in the EU since March 2011 and is authorised in Malta through the centralised procedure.

Information from European Medicines Agency about minimising risks of the rare brain infection PML and a type of skin cancer with Gilenya

The EMA has issued new advice for doctors and patients on the potential risks related to the immunosuppressive effect of the multiple sclerosis medicine Gilenya. Patients treated with Gilenya may be at higher risk of developing infections and diseases, including progressive multifocal leukoencephalopathy (PML) and some types of cancer such as basal cell carcinoma (BCC)

- Progressive multifocal leukoencephalopathy (PML) is a rare brain infection caused by John Cunningham (JC) virus. PML symptoms are similar to those of a multiple sclerosis attack and may result in severe disability or death.
- Basal cell carcinoma (BCC) is a slow-growing type of skin cancer which is almost never life-threatening but can be disfiguring if not treated promptly.
- Gilenya must not be used in patients with basal cell carcinoma, or any other type of cancer.

The product information for Gilenya will be updated with information about PML, basal cell carcinoma and other risks associated with the weakening of the immune system, in line with the new recommendations.

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In Malta

For Healthcare Professionals

Due to its immunosuppressive effects, Gilenya (fingolimod) may predispose patients to serious adverse reactions such as progressive multifocal leukoencephalopathy (PML), opportunistic infections including infections of the central nervous system, and cancers including basal cell carcinoma. Due to this doctors are encouraged (1) to be vigilant for early signs for symptoms suggestive of PML and (2) to be vigilant for skin lesions suggestive of basal cell carcinoma (BCC).

Summary of EMA recommendations for PML and BCC

- Before starting treatment with Gilenya, a baseline MRI scan should be available (usually within 3 months) as a reference.
- An MRI should be performed immediately If PML is suspected, and treatment with Gilenya should be suspended until PML has been excluded.
- A medical evaluation of the skin is recommended before starting treatment, after at least one year and then at least yearly during treatment with Gilenya.

Healthcare professionals are encouraged to refer to the product information and prescriber's checklist when prescribing Gilenya for MS. Further risk minimisation measures related to Gilenya can be accessed from the Medicines Authority's website here.

A DHPC related to the risk of PML and Gilenya had been approved by the Medicines Authority and was issued in April 2015 by Novartis Malta. This DHPC is available online here

Advice for Patients

Patients are encouraged to speak to their doctor as soon as possible;

- If they experience changes in mood or behaviour, memory lapses, speech and communication difficulties.
- If they feel their disease is getting worse or notice any new or unusual symptoms since symptoms of PML resemble symptoms of a multiple sclerosis attack
- If they notice any unusual skin lesions such as skin nodules, patches or open sores that do not heal within weeks.

Patient who have any questions or concerns are also encouraged to speak to their doctor or pharmacist. Patients are encouraged to refer to their **patient reminder card** and the patient information leaflet found in every box of Gilenya for more information.

For more information on this medicine please visit the European Medicines Agency's webpage on **Gilenya**

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Gilenya. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending to postlicensing.medicinesauthority@gov.mt or online at http://www.medicinesauthority.gov.mt/adrportal or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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