MALTA MEDICINES AUTHORITY

Review of Tysabri started

31.12.2015 | P17/2015

Information on Tysabri

- Tysabri (natalizumab) is a medicine used to treat adults with highly active multiple sclerosis (MS) specifically in the type of MS known as 'relapsing-remitting' MS.
- Tysabri was authorized in the European Union in June 2006 and is available in Malta via centralized procedure for hospital use

Information from European Medicines Agency about Tysabri and the risk of progressive multifocal leukoencephalopathy (PML)

The European Medicines Agency (EMA) has started a review of the multiple sclerosis medicine Tysabri (natalizumab) with the aim of assessing whether the advice given to healthcare professionals and patients on how to manage the known risk of progressive multifocal leukoencephalopathy (PML) with this medicine should be revised in the light of new scientific evidence.

- PML is a rare brain infection caused by John Cunningham virus (JCV), which has symptoms that may be similar to those of a multiple sclerosis attack, and may result in severe disability or death.
- Three important risk factors for PML; the presence of anti-JCV antibodies; Treatment duration; Prior immunosuppressant treatment.
- Scientific evidence on PML is rapidly growing and new data seem to indicate that the methods used to calculate the risk of PML may need to be revised and that testing for PML in patients with no symptoms may need to be performed more frequently than currently recommended.
- New diagnostic tests have recently been developed and there is a need to assess whether this has an impact on the current prescribing advice.

EMA will now evaluate the available data on the risk of PML with Tysabri with the aim of better defining the risk of PML and identifying further measures to minimize it. A European Commission decision on this opinion will be issued in due course

In Malta

For Healthcare Professionals

Prescribers should be aware of the possibility that PML may occur during Tysabri therapy. The following risk factors have been associated with development of PML during Tysabri treatment:

- The presence of anti-JCV antibodies
- Treatment duration.
- Prior immunosuppressant treatment.

Irrespective of the presence or absence of PML risk factors, heightened clinical vigilance for PML should be maintained in all patients treated with Tysabri

Physicians are encouraged to refer to the Summary of Product Characteristics (SmPC) and Physician Information and Management Guidelines for Multiple Sclerosis patients on Tysabri therapy provided by the marketing authorization holder and available online at www.medicinesauthority.gov.mt/rmm

Advice for Patients

Patients are reminded;

- To read the Package Leaflet each time that they take Tysabri because it may have new information that is important to their treatment.

- To keep the Alert Card with them to serve as reminder of the important safety information, in particular any symptoms that patients may develop which could possibly indicate PML.

Patients are encouraged to refer to the Patient Information Leaflet (PIL), Patient Alert Card and Treatment Initiation and Continuation Forms for more important safety information about progressive multifocal leukoencephalopathy (PML). Patients may ask their doctor for such information or find it online at www.medicinesauthority.gov.mt/rmm

For more information on Tysabri and PML please see the press release issued by the European Medicines Agency

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Tysabri. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form 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 Medicine Authority website for product safety updates as these are issued on an ongoing basis.