



IRISH MEDICINES BOARD

IMB Update on Use of Antiviral Medicines for Pandemic (H1N1) 2009 Influenza (1)

Antiviral medicines are available for the clinical management of pandemic (H1N1) 2009 influenza. Among the antiviral medicines that are authorised in the EU for use in an influenza outbreak, the neuraminidase inhibitors Tamiflu (oseltamivir) and Relenza (zanamivir) are two to which the A/H1N1 virus has shown susceptibility. Both products are authorised for use in Ireland and across the EU through European assessment procedures and full details of the currently available prescribing information for Tamiflu and Relenza are accessible from the IMB website at http://www.imb.ie/EN/Medicines/Pandemic_H1N1-2009.aspx

Updated Regulatory Recommendations

Following review of available data, the European Medicines Agency (EMA) has recently advised that **Tamiflu can be used in children under one year during the influenza pandemic**. The dose recommendation is 3mg/kg for treatment of children aged between 6 and 12 months during the influenza pandemic. As the available data for children aged between 0 to 6 months of age remain very limited, a precise dose could not be recommended for this age group and the EMA recommendation is to use 2-3mg/kg for this population.

The EMA has also issued guidance on the use of Tamiflu and Relenza in pregnant and breastfeeding women. The recommendation is that, due to the potentially serious risks of H1N1 swine influenza in pregnancy, the benefits of using Relenza and Tamiflu in treating influenza in pregnant or breastfeeding women outweigh any known risks.

In addition, the EMA also recommended in May that the shelf life of Tamiflu be extended from 5 to 7 years. A similar extension was approved for Relenza at the end of May.

Further information, including a detailed recent edition of the IMB Drug Safety Newsletter on Tamiflu and Relenza is available from the IMB website at

http://www.imb.ie/EN/Medicines/Pandemic_H1N1-2009.aspx and on the EMA website <http://www.emea.europa.eu>

Reporting of suspected adverse reactions to antiviral medicines

Increased exposure during the pandemic may reveal rare adverse reactions that have not previously been observed and, as such, the IMB is requesting that all suspected adverse reactions are promptly reported. A special web-based system for reporting suspected adverse reactions (ARs) to Tamiflu and Relenza has been developed. This on-line reporting system is accessible via the Pandemic webpage on the IMB homepage (<http://www.imb.ie>).

- Please report all suspected ARs to Tamiflu and Relenza via the Pandemic AR On-line reporting system at http://www.imb.ie/EN/Medicines/Pandemic_H1N1-2009.aspx
- It is of particular importance that serious adverse reactions should be notified promptly including cases where an antiviral medicine is thought to have been ineffective.
- Please remember to include the following important information in your report: Patient age, indication (prophylaxis or treatment), outcome of the AR, information on any underlying risk factors for the AR or for influenza complications; or state if there are no known risk factors, any other information about the patient or additional clinical details that will help us in our assessment of the case.
- When pandemic influenza A/H1N1 vaccines become available, the on-line reporting system should also be used to report suspected ARs to these vaccines.
- During the pandemic, the IMB recommends that healthcare professionals should, where feasible, report using the on-line reporting system. However, the Yellow Card system will remain in use and a downloadable report form can also be printed from the IMB website.

This section has been supplied by the IMB for use in MIMS Ireland. However, the IMB is independent and impartial to any other information contained in this directory