



European Medicines Agency
Press Office

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Press release
European Medicines Agency recommends no changes
for Tamiflu safety information

A review by the European Medicines Agency (EMA) of new safety data for Tamiflu has concluded that there is no new safety signal relating to psychiatric disorders while taking Tamiflu and therefore no change to the product safety information of Tamiflu is needed.

The Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP), made the review at its 12-14 December 2005 meeting. The CHMP reviewed cumulative safety data submitted by Roche on serious psychiatric disorders. This follows a request made by the CHMP to Roche in November 2005.

Tamiflu (the scientific name is oseltamivir) is an antiviral approved in the European Union for the treatment of influenza in children between 1 and 13 years of age and for the prevention and treatment of influenza in adolescents over 13 years and adults. The CHMP also gave a positive opinion at the 12-14 December 2005 meeting to extend the use of Tamiflu to include prevention of influenza in children between 1 and 13 years.

All adverse reactions of Tamiflu are monitored and assessed on a routine basis, as for all medicinal products. In addition, close monitoring of psychiatric disorders has been in place for Tamiflu since February 2003 at the request of the EMA, following the evaluation of safety information provided by Roche in November 2002. Further to the evaluation of the data submitted by Roche in November 2005, the CHMP concluded that close monitoring of psychiatric disorders should continue.

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NOTES:

1. The November 2005 safety update statement can be found [here](#).
2. More information on Tamiflu is available in the European public assessment report on the EMA website, which can be found [here](#).
3. A summary of the CHMP opinion recommending extension of use to include prevention of influenza in children between 1 and 13 years of age can be found [here](#).
The EMA has produced a summary report on the use of antivirals in case of pandemic influenza, which is available on the EMA website [here](#).
4. This press release, together with other information on the work of the EMA is available on the EMA website: <http://www.emea.eu.int>.

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