



PENNSYLVANIA PATIENT SAFETY ADVISORY

Produced by ECRI Institute
and ISMP under contract
to the Pennsylvania
Patient Safety Authority

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SUPPLEMENTARY ALERT

Confusion Regarding Concentration of Tamiflu® Oral Suspension

A shortage of commercially available Tamiflu® (oseltamivir phosphate) oral suspension is contributing to dosing errors in healthcare facilities. The Pennsylvania Patient Safety Authority has received two reports related to the concentration of Tamiflu. In each case, it was thought that the commercially available 12 mg/mL product and not a pharmacy-compounded 15 mg/mL suspension would be dispensed.

About the Pennsylvania Patient Safety Advisory

OBJECTIVE

The *Pennsylvania Patient Safety Advisory* provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Pennsylvania Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems and solutions; and those in which urgent communication of information could have a significant impact on patient outcomes.

PUBLISHING INFORMATION

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Current and previous issues are available online at <http://www.patientsafetyauthority.org>.

SUBSCRIPTION INFORMATION

This publication is disseminated by e-mail at no cost to the subscriber. To subscribe, go to <https://www.papsrs.state.pa.us/Workflow/MailingListAddition.aspx>.

INDEX INFORMATION

The *Pennsylvania Patient Safety Advisory* is indexed in the Cumulative Index to Nursing and Allied Health Literature® (CINAHL®) print index and electronic database.

CONTINUING MEDICAL EDUCATION

The Pennsylvania Patient Safety Authority works with the Pennsylvania Medical Society to offer AMA PRA Category 1 Credits™ for selected portions of the *Pennsylvania Patient Safety Advisory* through the online publication *Studies in Patient Safety*. Go to <http://www.pamedsoc.org> to find out more about patient safety CME opportunities.



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Manuscripts consistent with the objectives of the *Pennsylvania Patient Safety Advisory* are welcome. For information and guidance about submission and instructions for authors, please contact the editor.

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Confusion Regarding Concentration of Tamiflu® Oral Suspension

A shortage of commercially available Tamiflu® (oseltamivir phosphate) oral suspension is contributing to dosing errors in healthcare facilities. On October 15, 2009, the Institute for Safe Medication Practices (ISMP) alerted healthcare professionals about a risk of overdoses and underdoses related to the concentration of *pharmacy-compounded* Tamiflu being dispensed in response to shortages of the manufacturer's oral suspension.¹ As of October 20, 2009, two reports have been submitted to the Pennsylvania Patient Safety Authority describing dosing errors related to the concentration of Tamiflu available from inpatient pharmacies. In each case, it was thought that the commercially available 12 mg/mL product and not a pharmacy-compounded 15 mg/mL oral suspension would be dispensed. Both pediatric patients received overdoses without harm.

The patient was ordered 60 mg of Tamiflu oral suspension, which was profiled using the 12 mg/mL concentration. 15 mg/mL was dispensed and 5 mL were administered. The error was noted and corrected. The physician was aware.

The patient started on Tamiflu 12 mg/mL oral suspension at a dose of 45 mg (equals 3.75 mL). 3.75 mL were drawn up using the 15 mg/mL concentration, making a dose of 56.25 mg.

Roche commercially manufactures Tamiflu oral suspension in a 12 mg/mL concentration (oseltamivir base) for pediatric and adult patients who have difficulty swallowing capsules (see Figure). In light of the influenza epidemic, pharmacies in some areas across the state and the nation have been unable to purchase the commercial oral suspension from the manufacturer or drug wholesalers. As a result, pharmacists have begun to compound the product according to the U.S. Food and Drug Administration-approved directions for the emergency compounding of an oral suspension listed in the Tamiflu labeling (<http://www.tamiflu.com/hcp/dosing/extprep.aspx>). The extemporaneously prepared suspension utilizes the powder in Tamiflu capsules, which remain available for purchase. However, use of the compounding directions found in the labeling results in a 15 mg/mL oseltamivir base concentration, not the commercially available 12 mg/mL base concentration. More information about Tamiflu as well as a free Webinar illustrating the emergency compounding process can be found at the influenza section of the RocheExchange (<http://www.rocheexchange.com/influenza>).

Alert healthcare practitioners in your facility to this situation. At this time, ISMP recommends that prescribers communicate suspension doses in mg rather than by volume.¹ Computerized prescriber order-entry systems should only list the available concentration on computer selection screens. Pharmacy computer systems should alert practitioners to verify the dose

Figure. Tamiflu® Oral Suspension 12 mg/mL



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and concentration to be dispensed. Proactive, direct communication between the prescriber and pharmacist may be necessary to ensure the intended dose reaches the patient. Include the patient specific dose with corresponding number of mL and the concentration of liquid provided on the pharmacy-generated label applied to the dispensed product.²

If pharmacists are experiencing a shortage of commercial Tamiflu oral suspension, ISMP suggests proactively communicating with prescribers at health system-owned physician practices and other area medical practices to advise them of the shortage and steps to reduce the possibility of dosing errors when dispensing the pharmacy-compounded solution. As an alternative, Tamiflu capsules may be opened and the contents (30 mg, 45 mg, and 75 mg) mixed with sweetened liquids, such as regular or sugar-free chocolate syrup, for single doses.³

Notes

1. Institute for Safe Medication Practices. Tamiflu oral suspension shortage contributing to dosing errors [special alert]. ISMP Med Saf Alert [online]. 2009 Oct 15 [cited 2009 Oct 22]. Available from Internet: <http://www.ismp.org/safetyalerts/20091015-Tamiflu.asp>.
2. Institute for Safe Medication Practices. Principles of designing a medication label for oral liquids for patient specific, inpatient use [online]. [cited 2009 Oct 22]. Available from Internet: <http://www.ismp.org/Tools/guidelines/labelFormats/liquidSolids.asp>.
3. Roche Laboratories, Inc. Tamiflu® (oseltamivir phosphate) [full prescribing information] [online]. 2008 Aug. [cited 2009 Oct 20]. Available from Internet: <http://www.gene.com/gene/products/information/tamiflu/pdf/pi.pdf>.

PENNSYLVANIA PATIENT SAFETY ADVISORY

THE PENNSYLVANIA PATIENT SAFETY AUTHORITY AND ITS CONTRACTORS



The Pennsylvania Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI Institute, as contractor for the Authority, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the Pennsylvania Patient Safety Authority, see the Authority’s Web site at <http://www.patientsafetyauthority.org>.



ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for nearly 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute’s expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures and drug technology.



The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a nonpunitive approach and systems-based solutions.