CORRESPONDENCE

Risk of Confusion in Dosing Tamiflu Oral Suspension in Children

TO THE EDITOR: The medical community should be made aware of the serious potential for dosing errors in children prescribed Tamiflu (oseltamivir) oral suspension, as illustrated in the case described below.

After the diagnosis of novel H1N1 influenza, a 6-year old received a prescription for Tamiflu (oseltamivir) oral suspension (12 mg per milliliter) at a dose of 3/4 teaspoon PO BID. However, the parents, one a primary care physician and the other one of the authors, had great difficulty determining the correct dose to administer to their child. The medication bottle was accompanied by a prepackaged syringe with markings of 30, 45, and 60 mg (Fig. 1). The label attached by the pharmacy specified the dose in volume units ("3/4 teaspoonful") but the syringe provided only markings in mass units (milligrams). Despite the disparate directions, the parents were eventually able to determine the correct dose with the aid of 1 of 10 tables in the portion of the package insert intended for prescribers, not for parents. Specifically, they solved the following equation for the milligram equivalent of the 3/4-tsp dose: 5 ml (volume of a teaspoon) × 0.75 × 12 mg per milliliter Tamiflu suspension = 45 mg on the syringe.

Most families and caregivers would not be able to identify or perform the cumbersome calculations required to administer Tamiflu safely to children, because the instructions on the pharmacy label, on the manufacturer's printed label, and in the accompanying Consumer Medication Information and the prepackage dosing syringe are misaligned. Thus, there is a high chance for dosing errors, compromised treatment, or toxic effects. Even more complex dosing and measurement calculations[1] will be required under the Emergency Use Authorization,[2] which has extended the use of oseltamivir to children under the age of 1 year.

Figure 1. Tamiflu Package, Label, and Syringe Included in Box.

Unless immediate steps are taken to improve the prescribing instructions for this drug in children, its safe use will be compromised. We recommend that all pharmacies be instructed to ensure that the label instructions for use are in the same dosing units as those on the measurement device dispensed with oseltamivir. For instance, in the present case, the instructions could have said, "fill the attached syringe to the level marked 45 mg and administer this amount twice a day for 5 days." If a prescription specifies the dose in teaspoons, only a syringe calibrated in fractions of a teaspoon should be dispensed and the instructions adjusted accordingly; if a prescription specifies the dose in milliliters, only a syringe calibrated in milliliters should be

used. In addition, the Consumer Medication Information must be improved and the public alerted to the potential for oseltamivir dosing errors. In the future, all measuring devices for use in children should be marked with volumetric doses (milliliters or teaspoons).

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Dr. Wolf reports receiving consulting fees from Abbott and Pfizer and grant support from McNeil Pharmaceuticals, and Dr. Wood reports being a partner and investor in Symphony Capital, serving as a director of Oxigene Pharmaceuticals, and receiving consulting fees from International Reinsurance companies. No other potential conflict of interest relevant to this letter was reported.

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1. Centers for Disease Control and Prevention. Emergency use authorization of Tamiflu: fact sheet for patients and parents. July 14, 2009. (Accessed September 22, 2009, at http://www.cdc.gov/h1n1flu/eua/pdf/tamiflu-patients.pdf.)

2. *Idem.* Emergency use authorization (EUA) of medical products and devices: Tamiflu (oseltamivir). (Accessed September 22, 2009, at http://www.cdc.gov/h1n1flu/eua/pdf/fda_letter_tamiflu.pdf.)