



Dutchess County Department of Health Public Health Alert*

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FDA Releases Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions

Date: November 5, 2009 - 5:00 pm

Please Distribute to Pharmacists

- In preparation for potential shortages, the FDA recently released guidance for **EMERGENCY Compounding TAMIFLU (oseltamivir phosphate) Capsules 75 mg to an oral suspension with a final concentration of 15 mg/ml for more than one patient. Please note this guidance is not to be used for convenience or when the FDA-approved TAMIFLU for Oral Suspension is commercially available.**
- Dutchess County has experienced and increase in Influenza-like Illnesses. Dutchess County Department of Health (DCDOH) is expecting this trend to continue throughout the coming months.
- DCDOH recommends pharmacies to review their current stock of influenza treatment medications such as Tamiflu (oseltamivir) and Relenza (zanamivir) and order additional supplies to meet expected increase in demand.
- Pharmacists can sign up for electronic notification of public health alerts at <http://www.co.dutchess.ny.us/CountyGov/Departments/Health/16586.htm>

Commercially manufactured Tamiflu for Oral Suspension (12 mg/mL) is the preferred product for pediatric and adult patients who have difficulty swallowing capsules. It may be necessary to prepare oral suspension from the 75 mg Tamiflu Capsules, as described in the FDA-approved labeling resulting in a concentration of 15 mg/ml when the commercial oral suspension, Tamiflu (12 mg/ml), is not readily available in a timely manner because of an actual shortage of the product.

If demand is high, the FDA will not object if pharmacies compound the suspension from Tamiflu Capsules in advance of receiving prescriptions, if the amount compounded is commensurate with the number of valid prescriptions that the pharmacy can reasonably anticipate receiving within the next 24 hours.

Pharmacies should carefully review the Tamiflu Capsule label for compounding the suspension instructions and review the FDA guidance in full: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm188629.htm>

END

*Health Alert- conveys the highest level of importance; warrants immediate action or attention; Health Advisory- provides important information for a specific incident or situation; may not require immediate action; Health Update- provides updated information regarding an incident or situation; unlikely to require immediate action.

Dutchess County Department of Health

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