

October 15, 2009
OKHAN-133-09-10-15-ADV-N

Pediatric Oseltamivir (Tamiflu®) Suspension Available from County Health Departments for Patients Meeting Eligibility Criteria

Due to the ongoing 2009 H1N1 Pandemic, a national shortage of oseltamivir (Tamiflu®) suspension has occurred. Although pharmacies can provide a compounded oseltamivir suspension for pediatric patients, the out-of-pocket cost for many families without insurance coverage or medication benefits can be significant. To help alleviate this situation, the Centers for Disease Control & Prevention (CDC) recently shipped expired lots of oseltamivir suspension previously cached in the Strategic National Stockpile to state health departments for distribution within their public health jurisdiction. Although the antiviral medication has reached expiration, the U.S. Food & Drug Administration (FDA) has performed testing of 26 different lots of Tamiflu for Oral Suspension as part of the federal government's Shelf Life Extension Program (SLEP) and has determined that data from scientific testing and analysis supports the use of these lots beyond their expiration dates. The FDA has further authorized the use of these lots beyond their expiration dates under an Emergency Use Authorization (EUA) (www.cdc.gov/h1n1flu/eua).

The Oklahoma State Department of Health (OSDH) is announcing availability of the re-distributed Tamiflu oral suspension at no cost to Oklahoma healthcare providers and pharmacies for treatment of pediatric patients with influenza illness meeting criteria described below. In Oklahoma and Tulsa Counties, the antiviral suspension can be accessed from the respective County Social Services Pharmacy (contact information provided at end of this advisory). In all other counties, healthcare providers are instructed to contact their respective local county health department (CHD) for more information.

The CHD cannot serve as a dispensary. Therefore, it is preferred that a representative of the requesting physician make arrangements to obtain the antiviral medication from the CHD. In some instances, personnel from the CHD may be able to transport the medication to the medical clinic. Upon receipt of the Tamiflu suspension, the physician or pharmacy will need to sign a brief provider agreement for use of the medication. **Under no circumstances should a parent/guardian be instructed to pick up the Tamiflu suspension from the CHD.**

Patient Eligibility Criteria:

- Patient is experiencing signs and symptoms consistent with influenza.
- Symptoms have been present for less than 48 hours.
- Child has an underlying medical condition that places him/her at increased risk for complications due to influenza, including but not limited to chronic pulmonary disease, asthma that requires medication for control, heart disease, neurodevelopmental condition, diabetes, hematologic disorder, or immunosuppressive condition.
- Parent or guardian lacks financial means or insurance coverage to purchase retail antiviral medication.

Note: Medicaid coverage does extend to compounded medications.

Pediatric Oseltamivir Dosing Guidelines

Antiviral medication dosing recommendations for treatment or chemoprophylaxis of 2009 H1N1 infection.
(Table extracted from product information for Tamiflu® and Relenza®)

Medication		Treatment (5 days)	Chemoprophylaxis (10 days)
Oseltamivir			
Adults			
		75-mg capsule twice per day	75-mg capsule once per day
Children ≥ 12 months			
Body Weight (kg)	Body Weight (lbs)		
≤15 kg	≤33lbs	30 mg twice daily	30 mg once per day
> 15 kg to 23 kg	>33 lbs to 51 lbs	45 mg twice daily	45 mg once per day
>23 kg to 40 kg	>51 lbs to 88 lbs	60 mg twice daily	60 mg once per day
>40 kg	>88 lbs	75 mg twice daily	75 mg once per day
Zanamivir			
Adults			
		10 mg (two 5-mg inhalations) twice daily	10 mg (two 5-mg inhalations) once daily
Children (≥7 years or older for treatment, ≥5 years for chemoprophylaxis)			
		10 mg (two 5-mg inhalations) twice daily	10 mg (two 5-mg inhalations) once daily

Note: Health care providers and pharmacists should be aware that an oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations is provided with TAMIFLU® for Oral Suspension, rather than graduations in milliliters (mL) or teaspoons (tsp). There have been cases where the units of measure on the prescription instructions (mL, tsp) do not match the units on the dosing device (mg), which has lead to patient or caregiver confusion and dosing errors. When dispensing commercially manufactured TAMIFLU® for Oral Suspension, pharmacists should ensure the units of measure on the prescription instructions match the dosing device. If prescription instructions specify administration using milliliters (mL) or teaspoons (tsp), then the device included in the Tamiflu® product package should be removed and replaced with an appropriate measuring device, such as an oral syringe if the prescribed dose is in milliliters (mL).

Treatment and Chemoprophylaxis for Children younger than 1 Year of Age

Children younger than 1 year of age are at higher risk for influenza-related complications and have a higher rate of hospitalization compared to older children. Oseltamivir is not approved for use in children younger than 1 year of age. However, limited safety data on oseltamivir treatment of seasonal influenza in children younger than 1 year of age suggest that severe adverse events are rare. Oseltamivir is authorized for emergency use in children younger than 1 year of age under an EUA issued by FDA, subject to the terms and conditions of the EUA. (<http://www.cdc.gov/h1n1flu/eua/tamiflu>)

Dosing recommendations for antiviral treatment or chemoprophylaxis of children younger than 1 year using oseltamivir.

Age	Recommended treatment dose for 5 days	Recommended prophylaxis dose for 10 days
Younger than 3 months	12 mg twice daily	Not recommended unless situation judged critical due to limited data on use in this age group
3-5 months	20 mg twice daily	20 mg once daily
6-11 months	25 mg twice daily	25 mg once daily

When dispensing TAMIFLU® for Oral Suspension for children younger than 1 year of age, the oral dosing dispenser that is included in the Tamiflu package should always be removed. Pharmacists and health care providers should provide an oral syringe that is capable of accurately measuring the prescribed milliliter (mL) dose, and counsel the caregiver how to administer the prescribed dose.

The full text of the current CDC Guidelines for use of antiviral medications in the treatment and prevention of influenza during the 2009-10 Season can be found at:

<http://www.cdc.gov/h1n1flu/recommendations.htm>

Agency: Oklahoma State Department of Health			
Notification ID: 133	Date: 10/15/2009	Time: 5:00pm	
Severity: Moderate	Acknowledgement: No	Sensitive: No	Status: Actual
Notification Type: Advisory	Reference: None	Dissemination: As Needed	

Categories of Health Alert messages:

Health Alert highest level of notification that the Oklahoma State Department of Health will send out. This usually refers to an immediate threat to the OSDH community and requires immediate action.

Health Advisory advises medical providers of a condition in the area. These are usually not medical emergencies. These may not require immediate action.

Health Update provides updates on previous alerts or advisories. These are unlikely to require immediate action.

This advisory has been distributed to Primary Care Physicians, Emergency Departments, and State and Local Health Officials

=====

You have received this message based upon the information contained within our emergency notification database. If you have a different or additional e-mail or fax address that you would like us to use please contact the OSDH Acute Disease Service at (405) 271-4060.

=====

County Social Services Pharmacy Contacts in Oklahoma County

Oklahoma County Pharmacy Location #1 (OKLAHOMA COUNTY SOCIAL SERVICES DEPARTMENT)

7401 Northeast 23rd Street, Oklahoma City, Ok 73141; Phone 405-713-1893

Hours: Monday, Tuesday, Thursday, & Friday

8:00 am to Noon and 1:00 pm to 3:30 pm

Closed on Wednesdays and major holidays

Oklahoma County Pharmacy Location #2 (OKLAHOMA COUNTY SOCIAL SERVICES DEPARTMENT)

222 Northwest 12th Street, Oklahoma City, Ok 73106; Phone 405-602-1470

Located in Good Shepherd Ministries Ramirez Center (12th & Robinson)

Hours: Mondays & Wednesdays Only

8:30am to 11:30am and 12:30pm to 3:00pm

Closed on major holidays

Mary Mahoney Memorial Health Center

12716 N.E. 36th Street

Spencer, OK 73084

(405) 769-3301

Hours: Monday – Wednesday: 8 a.m. – 8 p.m.; Thursday: 8 a.m. – 5 p.m.; Friday: 10 a.m. – 5 p.m.

Perry A. Klaassen Family Medical Center

201 N.E. 48th Street

Oklahoma City, OK 73105

(405) 521-8486

Hours: Monday – Wednesday: 8 a.m. – 8 p.m.; Thursday: 8 a.m. – 5 p.m.; Friday: 10 a.m. – 5 p.m.

Closed Saturday and Sunday.

During an emergency hours and days of operation can be extended, as necessary.

County Social Services Pharmacy Location and Contact in Tulsa County

Tulsa County Pharmacy Location

Linda Johnston

Tulsa County Social Services

2401 Charles Page Blvd.

Tulsa, OK 74127

(918) 596-5561

LJohnston@TulsaCounty.org

Hours: Monday - Friday 8:30 a.m -12:00 p.m and 12:30 p.m. - 4:30 p.m.

Morton Comprehensive Health Center

Teola Trent Gay

1334 N. Lansing Ave.

Tulsa, OK 74106

(918) 295-6125 or (918) 906-6984

TGay@MortonHealth.org

Hours: Monday, Wednesday, Friday 8:30 a.m. – 5:30 p.m.; Tuesday 9:30 a.m – 6:30 p.m.;

Thursday 10:00 a.m. – 5:30 p.m.