State of Tennessee Department Of Health Stockpile Antiviral Distribution

September 24, 2009

(This document replaces the May 2009 guidance)

CONTENTS

Objective:
To make antiviral treatment available to patients with influenza who are at high risk for complications and do not have financial resources to pay for medication.

Concept of Operations:
Individuals presenting with influenza-like symptoms entering the health department clinic will be asked to wear a mask and practice respiratory etiquette and follow hand hygiene per CDC/TDH recommendations. The patient will be evaluated to ensure they meet established criteria for the allocation of antivirals. Healthcare providers will keep patients suspected of having H1N1 influenza in the health clinic for the shortest period of time possible to reduce the potential for transmission of the virus. Patients for whom it is decided Tamiflu® is appropriate will need a prescription or written order documented in the patient chart from a licensed healthcare provider in a State Health Department primary care clinic or metropolitan County Health Department-associated/partnering clinic. Tamiflu® (oseltamivir) and instructions for use will be provided to patients who meet the criteria listed on the **Tamiflu® (Oseltamivir) Dispensing Checklist for Suspected Cases of Pandemic H1N1 Influenza**.

Medication Distribution:
Tamiflu® (oseltamivir) will be shipped to each State Health Department primary care clinic and metropolitan County Health Department-associated/partnering clinic. Electronic copies of the patient fact sheets will be provided. The oral dispenser that accompanies the Tamiflu® suspension from the manufacturer has graduations of 30 mg, 45 mg, and 60 mg, thus children < 1 year old **will not** be dosed appropriately using the supplied dispenser. The healthcare worker issuing the medication must refer to the dosing chart below. The allocation and shipment of the antivirals and fact sheets to local health department clinics and other dispensing sites will be the responsibility of each Regional Health office.

Tamiflu® (oseltamivir) Medication Dosing Chart

Age Group	Weight Group (lbs.)	Dosage			
		Treatment (5 day)	Prophylaxis (10 day)	Volume per Dose	Number of Bottles
< 3 months		12 mg twice daily	Not recommended	1 mL	1
3-5 months		20 mg twice daily	20 mg once daily	1.6 mL	1
6-11 months		25 mg twice daily	25 mg once daily	2 mL	1
1-2	≤ 33 pounds	30 mg twice daily	30 mg once daily	2.5 mL (½ tsp)	1
3-5	>33 - 51	45 mg twice daily	45 mg once daily	3.8 mL (¾ tsp)	2
6-9	51 – 88	60 mg twice daily	60 mg once daily	5 mL (1 tsp)	2
≥ 10	> 88	75 mg twice daily	75 mg once daily	6.2 mL (1¼ tsp)	3
Renal Dose Adjustment CrCl 10-30 mL/min		75 mg once daily	75 mg every other day	6.2 mL (1¼ tsp)	3

Preparation of Tamiflu® for Oral Suspension

Tamiflu® for Oral Suspension may be reconstituted by a pharmacist, APN, MD, or DO. To ensure that the patient receives the appropriate dilution and dose of the medication a constituted bottle with labeling that includes the accurate concentration and directions for taking the medication with the type of dispenser supplied must be provided prior to leaving the clinic.

1. Tap the closed bottle several times to loosen the powder.
2. Measure **23 mL** of water in a graduated cylinder.
3. Add the **23mL** of water to the bottle and shake the closed bottle well for 15 seconds.
4. Remove the child-resistant cap and push bottle adapter into the neck of the bottle.
5. Close bottle with child-resistant cap tightly. This will assure the proper seating of the bottle adapter in the bottle and child-resistant status of the cap.
6. Constituted Tamiflu® for Oral Suspension should be refrigerated (36° - 46°F), and discarded after 10 days of refrigeration.

Note: This reconstitution results in a concentration of 12 mg/mL suspension.

If Tamiflu® for Oral Suspension is unavailable, a pharmacist or MD may compound the pediatric dosage form following the FDA approved package insert emergency compounding instructions found on page 19-21 of the manufacturer's website:
http://www.rocheusa.com/products/tamiflu/ppi.pdf.
The expiration for compounded Tamiflu® suspension is 5 weeks (35 days) when refrigerated and five days (5 days) when stored at room temperature.

Note: This compounding procedure results in a concentration of 15 mg/mL suspension, which is different from the commercially available product.

Instructions on Patient Use of Commercially Available Reconstituted Tamiflu® Suspension:

The patient/caregiver must be instructed on:

1. The appropriate dosage and frequency of medication to be administered
2. How to appropriately measure the dose with one of the dispensers below that will be supplied with the medication:
   - -Tamiflu® oral dispenser
   - -Graduated dosing spoon
   - -Oral syringe
3. Appropriate storage requirements for oral suspension: refrigerated (36° - 46°F), and discarded after 10 days of refrigeration for commercially available product. For the compounded product, discard after 5 weeks (35 days) if stored under refrigeration or five days (5 days) if stored at room temperature.

Documentation Requirements for Health Department Primary Care Clinic Setting:

The standard documentation on each patient dispensed Tamiflu® will be:

1) Patient prescription or written order from APN, MD, or DO in the patient chart
2) Complete and retain the Dispensing Checklist for Suspected Cases of Novel H1N1 Influenza (*see attached*) in one group file for follow-up as requested by TDH. It is not necessary to file in the patient chart, nor to identify by patient name.
3) Document encounter in PTBMIS, provider will code encounter and enter medication into the patient profile as usual for a visit
4) Provide the patient with the ***Tamiflu® Patient Emergency Use Authorization Fact Sheet July Update*** and if dispensing the commercially available Tamiflu® Oral Suspension, provide the ***Date Slip***, as appropriate.

Documentation Requirements for Non-Health Department Clinic Setting:
The standard documentation on each patient dispensed Tamiflu® will be:
1) Patient prescription from licensed healthcare provider
2) Complete and retain the Dispensing Checklist for Suspected Cases of pandemic H1N1 influenza (*see attached*) in one group file for follow-up as requested by TDH.
3) Provide the patient with the ***Tamiflu® Patient Emergency Use Authorization Fact Sheet July Update*** and if dispensing the commercially available Tamiflu® Oral Suspension provide the ***Date Slip***, as appropriate.

Adverse Event Reporting:
Serious adverse events associated with the use of antiviral drugs should be reported by the patient to the local health department or healthcare provider. The provider will complete the FDA MEDWATCH Adverse Event Report Form 3500 and submit it to the FDA. The MEDWATCH form is available at:
www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf

Local health departments will send a copy of the completed MEDWATCH form to the Regional Pharmacist notifying them of any adverse events after submission of the MEDWATCH form to the FDA.

FDA Expiration Date Extension for TAMIFLU® (oseltamivir) for Oral Suspension
If the commercially available TAMIFLU® for Oral Suspension provided has an original expiration date that has passed, the product may have been included in the federal government Shelf Life Extension Program (SLEP). Products in the Program are tested for potency and deemed adequate for extension of the expiration. The federal government has provided a website, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962, to compare lot numbers of products to those that have had the expiration date extended. Health department staff should inform patients receiving the product of the new expiration date and provide a ***Date Slip*** (see attached).

Expiration Date Extension for commercially available TAMIFLU® for Oral Suspension:
Lot Number # B1187 **Old Date:** 6/30/2009 **FDA Extended Date:** 5/31/2011

TENNESSEE DEPARTMENT OF HEALTH
Bureau of Health Services

Dispensing Checklist for Suspected Cases of Pandemic H1N1 Influenza

Antiviral treatment for suspected cases of pandemic H1N1 influenza infection is currently recommended for hospitalized patients and patients at higher risk for influenza complications. Small amounts of Tamiflu® (Oseltamivir) are available for treatment of suspected cases of pandemic H1N1 influenza who cannot afford to purchase the medicine at a pharmacy. The provider must document dispensing either by prescription or written order from an APN, MD, or DO in the patient's chart and complete the following checklist.

Please provide patient age: _____ (required)

Check all that apply and dispense antiviral medicine only if **all 3 conditions** are met:

1. **Suspected case of influenza:**
   - ☐ Patient has influenza-like illness (fever >37.8°C/100°F and respiratory symptoms [cough or sore throat]) without another explanation
2. **Patient is at high risk for influenza complications (check which apply):**
   - ☐ Child younger than 5 years old. (The risk for severe complications from seasonal influenza is highest among children younger than 2 years old.)
   - ☐ Adult 65 years of age and older
   - ☐ Person with a high risk chronic condition:
     - ☐ Chronic pulmonary, including asthma
     - ☐ Cardiovascular, except hypertension
     - ☐ Renal
     - ☐ Hepatic
     - ☐ Hematological, including sickle cell disease
     - ☐ Neurologic
     - ☐ Neuromuscular
     - ☐ Metabolic disorders, including diabetes mellitus
   - ☐ Immunosuppression, including that caused by medications, HIV, or organ transplant
   - ☐ Pregnant woman
   - ☐ Person younger than 19 years of age who is receiving long-term aspirin therapy
   - ☐ Resident of nursing home and other chronic-care facility
   - ☐ Severely ill with flu-like symptoms
3. **Patient has no means to purchase antiviral medicine at a pharmacy**
   - ☐ Uninsured
   - ☐ No resources for payment

- Dosage and duration of therapy is the same as for seasonal influenza (see dosage sheet).
- Secondary bacterial infections are possible during any influenza illness (consider methicillin-resistant *Staphylococcus aureus* [MRSA])
- Details can be found at: http://www.cdc.gov/h1n1flu/recommendations.htm
- Review the algorithm for clinicians: http://health.state.tn.us/H1N1.htm

Prescribing provider signature: _____ (required)

EMERGENCY USE AUTHORIZATION of TAMIFLU®: FACT SHEET FOR HEALTH CARE PROVIDERS[1]

You have been asked as a health care provider to give TAMIFLU® (oseltamivir phosphate) to people who have been exposed to novel Influenza A (H1N1) (Swine Influenza A). TAMIFLU® is approved by the U.S. Food and Drug Administration (FDA) to treat and prevent influenza. Certain aspects of the emergency use are not part of the approved drug applications, such as use in pediatric patients less than 1 year old, use in patients who are symptomatic for more than 2 days, and use in patients who have complicated illness requiring hospitalization. **For more information,** refer to http://www.cdc.gov/h1n1flu or www.fda.gov.

Recommended Treatment Dosage

Adults and Adolescents 13 years and older: 75 mg twice daily for 5 days. Treatment should begin as soon as possible after symptom onset.

Pediatric Patients 1 to 12 years old: Dosage is shown in the following table. For pediatric patients who cannot swallow capsules, TAMIFLU® for Oral Suspension is the preferred formulation. If the oral suspension product is not available, TAMIFLU® Capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup.

Body Weight (kg)	Body Weight (lbs)	Age (years)	Dose for 5 Days	# Bottles of Oral Suspension Needed for the 5 Day Regimen	# of Capsules Needed for the 5 Day Regimen
≤ 15	≤ 33	1-2	30 mg twice daily	1	10 capsules (30 mg)
> 15-23	> 33-51	3-5	45 mg twice daily	2	10 capsules (45 mg)
> 23-40	> 51-88	6-9	60 mg twice daily	2	20 capsules (30 mg)
> 40	> 88	10-12	75 mg twice daily	3	10 capsules (75 mg)

An oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations is provided with TAMIFLU® for Oral Suspension; the 75 mg dose can be measured using a combination of 30 mg and 45 mg. It is recommended that patients use this dispenser. In the event that the dispenser provided is lost or damaged, another dosing syringe or other device may be used to deliver the following volumes: 2.5 mL (1/2 tsp) for children ≤ 15 kg, 3.8 mL (3/4 tsp) for > 15 kg to 23 kg, 5 mL (1 tsp) for > 23 kg to 40 kg, and 6.2 mL (1 ¼ tsp) for > 40 kg.

*Pediatric Patients less than 1 year old**

Body Weight (kg)	Dose by Age	Recommended Treatment Dose for 5 Days (Dose in volume is based on the concentration (12 mg/mL) of commercially-manufactured TAMIFLU® Oral Suspension)
Dosing for infants younger than 1 year not based on weight	< 3 months	12 mg (1 mL) twice daily
	3-5 months	20 mg (1.6 mL) twice daily
	6-11 months	25 mg (2 mL) twice daily

*For more information regarding the basis for dose recommendations, see FDA's "Tamiflu Technical Review Document for H1N1 Influenza A" on www.cdc.gov/h1n1flu or www.fda.gov.

For infants less than 1 year old, a different measuring device (such as a 5-mL oral syringe) must be used to correctly measure the dose.

Recommended Prophylaxis Dosage

Adults and Adolescents 13 years and older: 75 mg once daily for at least 10 days following close contact with an infected person. Therapy should begin as soon as possible after exposure. The recommended dose for prophylaxis during a community outbreak of influenza is 75 mg once daily. Safety and efficacy have been demonstrated for up to 6 weeks. The duration of protection lasts for as long as dosing is continued.

Pediatric Patients 1 to 12 years old: Dosage following close contact with an infected individual is shown in the following table. For pediatric patients who cannot swallow capsules, TAMIFLU® for Oral Suspension is the preferred formulation. If the oral suspension product is not available, TAMIFLU® Capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup.

[1] In the event of an emergency, it is possible that public health officials or other volunteers might distribute TAMIFLU® products to recipients as authorized. In this fact sheet, the term "health care provider(s)" includes these individuals and is used for brevity here.

Body Weight (kg)	Body Weight (lbs)	Dose by Age (years)	Dose for 10 Days	# Bottles of Oral Suspension Needed for the 10 Day Regimen	Number of Capsules Needed for the 10 Day Regimen
≤ 15	≤ 33	1-2	30 mg once daily	1	10 capsules (30 mg)
> 15-23	> 33-51	3-5	45 mg once daily	2	10 capsules (45 mg)
> 23-40	> 51-88	6-9	60 mg once daily	2	20 capsules (30 mg)
> 40	> 88	10-12	75 mg once daily	3	10 capsules (75 mg)

An oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations is provided with TAMIFLU® for Oral Suspension; the 75 mg dose can be measured using a combination of 30 mg and 45 mg. It is recommended that patients use this dispenser. In the event that the dispenser provided is lost or damaged, another dosing syringe or other device may be used to deliver the following volumes: 2.5 mL (1/2 tsp) for children ≤ 15 kg, 3.8 mL (3/4 tsp) for > 15 kg to 23 kg, 5 mL (1 tsp) for > 23 kg to 40 kg, and 6.2 mL (1 ¼ tsp) for > 40 kg.

Prophylaxis in pediatric patients following close contact with an infected individual is recommended for 10 days. Prophylaxis in patients 1 to 12 years of age has not been evaluated for longer than 10 days duration. Therapy should begin soon as possible.

*Pediatric Patients less than 1 year old**

Body Weight (kg)	Dose by Age	Recommended Prophylaxis Dose for 10 Days (Dose in volume is based on the concentration (12 mg/mL) of commercially-manufactured TAMIFLU® for Oral Suspension)
Dosing for infants younger than 1 year not based on weight	< 3 months	Not recommended unless situation judged critical
	3-5 months	20 mg (1.6 mL) once daily
	6-11 months	25 mg (2 mL) once daily

*For more information regarding the basis for dose recommendations, see FDA's "Tamiflu Technical Review Document for H1N1 Influenza A" on www.cdc.gov/h1n1flu or http://www.fda.gov.

For infants less than 1 year old, a different measuring device (such as a 5-mL oral syringe) must be used to correctly measure the dose.

Special Dosage Instructions

No dose adjustment is recommended for patients with mild or moderate hepatic impairment (Child-Pugh score ≤ 9). No dose adjustment is required for geriatric patients.

Renal Impairment, Recommended Treatment Dosage: Dose adjustment is recommended for patients with creatinine clearance between 10 and 30 mL/min. Treatment dose should be reduced to 75 mg once daily for 5 days. No recommended dosing regimens are available for patients undergoing routine hemodialysis and continuous peritoneal dialysis treatment with end-stage renal disease.

Renal Impairment, Recommended Prophylaxis Dosage: Dose adjustment is recommended for patients with creatinine clearance between 10 and 30 mL/min receiving TAMIFLU®. In these patients it is recommended that the dose be reduced to 75 mg of TAMIFLU® every other day or 30 mg TAMIFLU® every day. No recommended dosing regimens are available for patients undergoing routine hemodialysis and continuous peritoneal dialysis treatment with end-stage renal disease.

Preparation of TAMIFLU® for Oral Suspension

TAMIFLU® for Oral Suspension may be constituted by a pharmacist or health care provider.

1. Tap the closed bottle several times to loosen the powder.
2. Measure **23 mL** of water in a graduated cylinder.
3. Add the total amount of water for constitution to the bottle and shake the closed bottle well for 15 seconds.
4. Remove the child-resistant cap and push bottle adapter into the neck of the bottle.
5. Close bottle with child-resistant cap tightly. This will assure the proper seating of the bottle adapter in the bottle and child-resistant status of the cap.

NOTE: SHAKE THE TAMIFLU® FOR ORAL SUSPENSION WELL BEFORE EACH USE.

Store constituted suspension under refrigeration at 2-8°C (36-46°F). Do not freeze. The constituted TAMIFLU® for Oral Suspension (12 mg/mL) should be used within 10 days of preparation; the pharmacist, health care official, patient, or patient's parent or guardian should write the date of expiration of the constituted suspension on the label. The Fact Sheet for Patients and Parents and oral dispenser should be dispensed to the patient.

Expired TAMIFLU® for Oral Suspension

If you have been asked to distribute/dispense TAMIFLU® for Oral Suspension that is past its original labeled expiration date, please be aware that the expiration date may have been extended as part of the federal government's Shelf Life Extension Program (SLEP). Under SLEP, FDA conducts scientific testing to see if specific lots of TAMIFLU® can be used beyond the expiration dates originally printed on the label by the manufacturer. If the product passes testing, FDA determines that the shelf life of the product can be extended beyond the expiration dates originally printed on the label. **For any TAMIFLU® for Oral Suspension that is past its original labeled expiration date, you may look up the lot number at the following website to determine if the expiry date for this lot has been extended and for how long: www.cdc.gov/h1n1flu/eua. For TAMIFLU® for Oral Suspension whose expiration date has been extended, you may inform recipients of the new expiration date.**

What are the Possible Side Effects of TAMIFLU®?

The side effects reported most often in those people who took this drug were gastrointestinal (i.e., nausea and vomiting). Nausea and vomiting may be less severe if TAMIFLU® is taken with food.

Rare cases of anaphylaxis and serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme have been reported in post marketing experience with TAMIFLU®. TAMIFLU® should be stopped and appropriate treatment instituted if an allergic-like reaction occurs or is suspected.

There have been postmarketing reports of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving TAMIFLU®. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made but they appear to be uncommon based on TAMIFLU® usage data. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of TAMIFLU® to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior.

Refer to the Package Insert for more safety information.
Make available to recipients the information in the Fact Sheet for Patients and Parents

Reporting And Monitoring Adverse Events

Health care providers and recipients that experience adverse events or medication errors are encouraged to report to MedWatch at www.fda.gov/medwatch, by submitting a MedWatch Form 3500 (available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) or by calling 1-800-FDA-1088.

EMERGENCY USE AUTHORIZATION of TAMIFLU®: FACT SHEET FOR PATIENTS AND PARENTS

You have been given TAMIFLU® (oseltamivir phosphate) for either treatment or prevention of novel H1N1 flu virus (Swine Influenza A). You can decide whether to take this drug. Taking TAMIFLU® may help you/your child recover more quickly if you/your child have novel H1N1 flu or help keep you/your child from getting sick if you/your child have been exposed to novel H1N1 flu virus.

What is novel H1N1 flu?
Novel H1N1 (referred to as "swine flu" early on) is a new flu virus causing illness in people. This new virus was first detected in people in the United States in April 2009. Other countries, including Mexico and Canada, have reported people sick with this new virus. This virus is spreading from person-to-person, probably in much the same way that regular seasonal flu viruses spread.

What are the symptoms of novel H1N1 flu in humans?
The symptoms are similar to the symptoms of regular seasonal flu and include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people, especially children, have reported diarrhea and vomiting associated with novel H1N1 flu. In the past, severe illness (pneumonia and trouble breathing) and deaths have been reported with novel H1N1 flu infection in people. Like seasonal flu, novel H1N1 flu may cause worsening of underlying chronic medical conditions.

What is TAMIFLU®?
TAMIFLU® is a medicine that is approved by the U.S. Food and Drug Administration (FDA) to prevent and treat influenza.

Why is TAMIFLU® being used under an Emergency Use Authorization (EUA)?
An EUA is issued by the FDA to allow certain aspects of TAMIFLU® use during this emergency involving novel H1N1 flu. **For more information**, visit http://www.cdc.gov/h1n1flu/eua or http://www.fda.gov.

How much TAMIFLU® should my child or I take if my child or I have novel H1N1 flu?
The dose for adults and teenagers 13 years of age and older is 75 mg twice daily for 5 days. For infants and children 1 to 12 years old, dosing by weight is best, but if your child's weight is not known, age can be used as shown in the table below. Treatment should start as soon as possible after the onset of symptoms and should be taken for 5 days.

Body Weight (kg)	**Body Weight (lbs)**	**Age**	**Recommended Treatment Dose for 5 Days**
Dosing for infants younger than 1 year is not based on weight. Use TAMIFLU® for Oral Suspension (12 mg per mL).		< 3 months	12 mg twice daily
		3-5 months	20 mg twice daily
		6-11 months	25 mg twice daily
≤ 15 kg	≤ 33 lbs	1-2 year	30 mg twice daily
> 15 kg to 23 kg	> 33 lbs to 51 lbs	3-5 years	45 mg twice daily
> 23 kg to 40 kg	> 51 lbs to 88 lbs	6-9 years	60 mg twice daily
> 40 kg	> 88 lbs	10-12 years	75 mg twice daily
Dosing for adults and teenagers 13 years and older is not based on weight.		13 years and older	75 mg twice daily

Tamiflu® for Oral Suspension that is made by Roche Laboratories, Inc., comes with an oral dispenser marked for 30 mg, 45 mg, or 60 mg. For children who weigh more than 40 kg (or 88 lbs) or adults who can't swallow capsules, you will need to measure out a dose of 30 mg plus another dose of 45 mg. For infants less than 1 year old, a different measuring device must be used that will dispense 2 mL (about 25 mg), 1.6 mL (about 20 mg) or 1 mL (12 mg). If you have any questions about the correct dose for you or your child, please contact your healthcare provider.

How much TAMIFLU® should my child or I take if my child or I have been exposed to novel H1N1 flu?
Doses for prevention of novel H1N1 flu are the same as those used for treatment as described in the above section, but are given only once a day rather than twice a day. Also, you should continue the medication for 10 days instead of 5 days. If you have any questions about correct doses for you or your child, please contact your healthcare provider.

What if my child or I cannot swallow capsules?
For pediatric patients who cannot swallow capsules, especially children less than 1 year old, TAMIFLU® for Oral Suspension is preferred. For children 1 year of age or older and adults who cannot swallow capsules, if the oral suspension is not available, the recommended dose of TAMIFLU® Capsule may be given by opening the capsule and mixing the powder with sweetened liquids such as regular or sugar-free chocolate syrup.

What are the possible benefits of taking TAMIFLU®?
If used for treatment, TAMIFLU® can benefit by stopping the flu virus from spreading inside the body. This can lead to improved symptoms of flu and quicker recovery. If you have been exposed to someone with the flu, taking TAMIFLU® can help keep the virus from making you sick.

What are the possible side effects from taking TAMIFLU®?
The most common side effects of TAMIFLU® are nausea and vomiting. These are not usually severe and usually happen in the first 2 days of treatment. Taking TAMIFLU® with food may reduce the chance of getting these side effects. Other events reported commonly by children treated with TAMIFLU® included abdominal pain, nosebleeds, ear problems, and pink eye. Side effects for children less than 1 year of age are not known, because there is little information on TAMIFLU® use in this age group.

If you develop an allergic reaction or severe rash, stop taking TAMIFLU® and contact your healthcare provider.

Children and teenagers with the flu may be at an increased risk of seizures, confusion, or abnormal behavior early during their illness. These events may occur shortly after beginning TAMIFLU® or may occur even when flu is not treated. These events are uncommon but may result in accidental injury to the patient. Therefore, children should be observed for signs of unusual behavior and a healthcare provider should be contacted immediately if the patient shows any signs of unusual behavior.

Is there an alternative treatment?
Yes. At this time, the Centers for Disease Control and Prevention (CDC) recommends the use of TAMIFLU® or RELENZA® (zanamivir) for the treatment and/or prevention of infection with novel H1N1 flu.

What if I decide not to treat myself or my child with TAMIFLU®?
It is your choice whether you or your child are treated with TAMIFLU®. You can decide not to take or stop taking it any time. It will not change your regular medical care.

What if my TAMIFLU® for Oral Suspension bottle shows it is expired?
If you were given a TAMIFLU® for Oral Suspension bottle that shows an expired date, you should know that the expiration date may have been extended based on scientific testing done by FDA. If the medicine passes FDA's tests, the expiration date of the medicine can be extended beyond the date originally printed on the bottle. To check on a specific bottle's expiration date, you may look up the lot number at the following website to determine if the lot has been extended and for how long: www.cdc.gov/h1n1flu/eua. If you have questions or wish to obtain further information, please contact the public health authority who gave you the TAMIFLU® for Oral Suspension.

How do I report side effects with TAMIFLU®?
Call your healthcare provider if you or your child experience side effects that bother you or your child or that do not go away. Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088.

How can I learn more?
If you have questions about your treatment, please refer to **www.cdc.gov/h1n1flu**

DATE SLIP

What if my Tamiflu® bottle shows it is out of date?

The federal government has tested Tamiflu®, Lot # B1187,
and found that it may be used for 2 more years, until May 31, 2011.

Questions? Go to: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.

Throw away any medicine left in the bottle after _____

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