

594 **Emergency Compounding of an Oral Suspension from TAMIFLU Capsules**
 595 **(Final Concentration 15 mg/mL)**

596 The following directions are provided for use only during emergency situations. These
 597 directions are not intended to be used if the FDA-approved, commercially manufactured
 598 TAMIFLU for Oral Suspension is readily available from wholesalers or the
 599 manufacturer.

600 Compounding an oral suspension with this procedure will provide one patient with
 601 enough medication for a 5-day course of treatment or a 10-day course of prophylaxis.

602 Commercially manufactured TAMIFLU for Oral Suspension (12 mg/mL) is the preferred
 603 product for pediatric and adult patients who have difficulty swallowing capsules or where
 604 lower doses are needed. In the event that TAMIFLU for Oral Suspension is not available,
 605 the pharmacist may compound a suspension (15 mg/mL) from TAMIFLU (oseltamivir
 606 phosphate) Capsules 75 mg using either of two vehicles: Cherry Syrup (Humco®) or
 607 Ora-Sweet® SF (sugar-free) (Paddock Laboratories). Other vehicles have not been
 608 studied. **This compounded suspension should not be used for convenience or when**
 609 **the FDA-approved TAMIFLU for Oral Suspension is commercially available.**

610 First, calculate the Total Volume of an oral suspension needed to be compounded and
 611 dispensed for each patient. The Total Volume required is determined by the weight of
 612 each patient. Refer to **Table 7**.

613 **Table 7 Volume of an Oral Suspension (15 mg/mL) Needed to be**
 614 **Compounded Based Upon the Patient’s Weight**

Body Weight (kg)	Body Weight (lbs)	Total Volume to Compound per patient (mL)
≤15 kg	≤33 lbs	30 mL
16 to 23 kg	34 to 51 lbs	40 mL
24 to 40 kg	52 to 88 lbs	50 mL
≥41 kg	≥89 lbs	60 mL

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616 Second, determine the number of capsules and the amount of vehicle (Cherry Syrup or
 617 Ora-Sweet SF) that are needed to prepare the Total Volume (calculated from Table 7:
 618 30 mL, 40 mL, 50 mL, or 60 mL) of compounded oral suspension (15 mg/mL). Refer to
 619 **Table 8**.

620 **Table 8 Number of TAMIFLU 75 mg Capsules and Amount of Vehicle**
 621 **(Cherry Syrup OR Ora-Sweet SF) Needed to Prepare the**
 622 **Total Volume of a Compounded Oral Suspension (15 mg/mL)**

Total Volume of Compounded Oral	30 mL	40 mL	50 mL	60 mL

Suspension needed to be Prepared				
Required number of TAMIFLU 75 mg Capsules	6 capsules (450 mg oseltamivir)	8 capsules (600 mg oseltamivir)	10 capsules (750 mg oseltamivir)	12 capsules (900 mg oseltamivir)
Required volume of vehicle Cherry Syrup (Humco) OR Ora-Sweet SF (Paddock Laboratories)	29 mL	38.5 mL	48 mL	57 mL

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624 Third, follow the procedure below for compounding the oral suspension (15 mg/mL)
625 from TAMIFLU Capsules 75 mg

- 626 1. Carefully separate the capsule body and cap and transfer the contents of the required
627 number of TAMIFLU 75 mg Capsules into a clean mortar.
- 628 2. Triturate the granules to a fine powder.
- 629 3. Add one-third (1/3) of the specified amount of vehicle and triturate the powder until a
630 uniform suspension is achieved.
- 631 4. Transfer the suspension to an amber glass or amber polyethyleneterephthalate (PET)
632 bottle. A funnel may be used to eliminate any spillage.
- 633 5. Add another one-third (1/3) of the vehicle to the mortar, rinse the pestle and mortar
634 by a triturating motion and transfer the vehicle into the bottle.
- 635 6. Repeat the rinsing (Step 5) with the remainder of the vehicle.
- 636 7. Close the bottle using a child-resistant cap.
- 637 8. Shake well to completely dissolve the active drug and to ensure homogeneous
638 distribution of the dissolved drug in the resulting suspension. (Note: The active drug,
639 oseltamivir phosphate, readily dissolves in the specified vehicles. The suspension is
640 caused by some of the inert ingredients of TAMIFLU Capsules which are insoluble in
641 these vehicles.)
- 642 9. Put an ancillary label on the bottle indicating "Shake Gently Before Use". [This
643 compounded suspension should be gently shaken prior to administration to minimize
644 the tendency for air entrapment, particularly with the Ora-Sweet SF preparation.]
- 645 10. Instruct the parent or guardian that any remaining material following completion of
646 therapy must be discarded by either affixing an ancillary label to the bottle or adding
647 a statement to the pharmacy label instructions.
- 648 11. Place an appropriate expiration date label according to storage condition (see below).
649

650 STORAGE OF THE PHARMACY-COMPOUNDED SUSPENSION:

651 **Refrigeration:** Stable for 5 weeks (35 days) when stored in a refrigerator at 2° to 8°C
652 (36° to 46°F).

653 **Room Temperature:** Stable for five days (5 days) when stored at room temperature,
654 25°C (77°F).

655 Note: The storage conditions are based on stability studies of compounded oral
656 suspensions, using the above mentioned vehicles, which were placed in amber glass and
657 amber polyethyleneterephthalate (PET) bottles. Stability studies have not been conducted
658 with other vehicles or bottle types.

659 Place a pharmacy label on the bottle that includes the patient’s name, dosing instructions,
660 and drug name and any other required information to be in compliance with all State and
661 Federal Pharmacy Regulations. **Refer to Table 9 for the proper dosing instructions.**

662 **Note: This compounding procedure results in a 15 mg/mL suspension, which is**
663 **different from the commercially available TAMIFLU for Oral Suspension, which**
664 **has a concentration of 12 mg/mL.**

665 **Table 9 Dosing Chart for Pharmacy-Compounded Suspension from**
666 **TAMIFLU Capsules 75 mg**

Body Weight (kg)	Body Weight (lbs)	Dose (mg)	Volume per Dose 15 mg/mL	Treatment Dose (for 5 days)	Prophylaxis Dose (for 10 days)
≤15 kg	≤33 lbs	30 mg	2 mL	2 mL two times a day	2 mL once daily
16 to 23 kg	34 to 51 lbs	45 mg	3 mL	3 mL two times a day	3 mL once daily
24 to 40 kg	52 to 88 lbs	60 mg	4 mL	4 mL two times a day	4 mL once daily
≥41 kg	≥89 lbs	75 mg	5 mL	5 mL two times a day	5 mL once daily

667 *Note: 1 teaspoon = 5 mL*

668 *Consider dispensing the suspension with a graduated oral syringe for measuring small*
669 *amounts of suspension. If possible, mark or highlight the graduation corresponding to*
670 *the appropriate dose (2 mL, 3 mL, 4 mL, or 5 mL) on the oral syringe for each patient.*
671 *The dosing device dispensed with the commercially available TAMIFLU for Oral*
672 *Suspension should NOT be used with the compounded suspension since they have*
673 *different concentrations.*



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2009-2010 Influenza Season: Information for Pharmacists

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Background

As of September 18, 2009 influenza activity is increasing in most of the United States with 21 states reporting widespread influenza activity. So far, most influenza viruses isolated are 2009 H1N1 flu (sometimes called "swine flu"), the virus that has been declared pandemic by the World Health Organization. CDC expects both 2009 H1N1 flu and seasonal flu to cause illness, hospital stays and deaths this influenza season and while influenza is unpredictable, it's possible the United States could experience an early, prolonged and severe influenza season.

CDC recommends a three-step approach to fighting the flu: vaccination, everyday preventive actions including frequent hand washing and staying home when sick, and the correct use of antiviral drugs if prescribed by a doctor.

CDC has issued recommendations for clinicians on the use of antiviral medications in the treatment and prevention of influenza for the 2009-2010 season. Oseltamivir (Tamiflu®) and zanamivir (Relenza®) are the two recommended influenza antiviral drugs at this time. The priority use for these drugs this season is to treat people who are very sick (hospitalized) or people who are sick with flu symptoms and who are at increased risk of serious flu complications, such as pregnant women, young children, people 65 and older and people with chronic health conditions.

The current situation will likely impact the nation's pharmacies as a greater number of people than usual seek to fill prescriptions for influenza antiviral drugs or antibiotics to treat secondary infections, in addition to seeking advice on over-the-counter flu medications. This may impact supplies and availability of antiviral medications and other materials that may be needed to fill such prescriptions.

Update on Antiviral Availability

At this time, CDC discussions with the antiviral supply chain (manufacturers, distributors and retailers) indicate that supplies of adult formulation (75 mg) oseltamivir (Tamiflu®) and zanamivir (Relenza®) are meeting current demand for this product. However, the Food and Drug Administration (FDA) and Roche (maker of Tamiflu®) have acknowledged that commercial and stockpiled supplies of Tamiflu® oral suspension are limited.

Pharmacies should be aware of the importance of providing patients with these influenza medications as quickly as possible when they are prescribed. Both Tamiflu® and Relenza® work best when administered within 48 hours of onset of symptoms. Having product at the pharmacy store level, including doses of oseltamivir and zanamivir and supplies to compound Tamiflu® if necessary, will be critical to ensuring that patients needing treatment receive it as quickly as possible.

Alternatives to Tamiflu® Oral Suspension for Pediatric Patients

FDA has a statement on their website

(<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm>)

reminding health care providers and pharmacists of the FDA-approved instructions for the emergency compounding of an oral suspension from Tamiflu® 75mg capsules as described in the [FDA approved manufacturer package insert for oseltamivir \(Tamiflu®\)](#) .

Compounding an oral suspension from Tamiflu® 75mg capsules provides an alternative when commercially manufactured oral suspension formulation is not readily available. Tamiflu® capsules 75 mg may be compounded using either of two vehicles: Cherry Syrup (Humco®) or Ora-Sweet® SF (sugar-free) (Paddock Laboratories). Other supplies needed to compound include mortar and pestle and amber glass or amber polyethyleneterephthalate (PET) bottle.

In addition, for children who may not be able to swallow capsules, Tamiflu® capsules may be opened and mixed with sweetened liquids, such as regular or sugar-free chocolate syrup, if oral suspension is not available.

Note on Tamiflu Oral Suspension Syringe

Pharmacists with access to Tamiflu® oral suspension should be aware that an oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations is provided in the packaging for the manufacturer's product rather than graduations in milliliters (mL) or teaspoons (tsp). There have been cases where the units of measure on the prescription dosing instructions (mL, tsp) do not match the units on the dosing device (mg), which can lead to patient or caregiver confusion and dosing errors. When dispensing commercially manufactured Tamiflu® oral suspension, pharmacists should ensure the units of measure on the dosing instructions match the dosing device provided. If dosing instructions specify administration using mL or tsp the device included in the Tamiflu® product package should be removed and replaced with an appropriate measuring device. When dispensing Tamiflu® oral suspension for children younger than 1 year of age, the oral dosing dispenser that is included in the product package should always be removed and replaced with an appropriate measuring device. (The Food and Drug Administration has issued [an Emergency Use Authorization \(EUA\) for the use of Tamiflu](#)  in pediatric patients younger than 1 year of age.)

CDC will provide additional information and updates as needed.

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