

# Compounding of an Oral Suspension from Oseltamivir Capsules

According to the US Food & Drug Administration (FDA), **in the event that oseltamivir (Tamiflu®) is in short supply**, pharmacists may compound a suspension (6 mg/mL)\* from oseltamivir 75 mg capsules using one of the following vehicles: Cherry Syrup (Humco®), Ora-Sweet® SF (sugar-free) (Paddock Laboratories) or simple syrup.<sup>1</sup> Other vehicles have not been specifically studied.

Steps for compounding are provided below. <sup>1</sup>

## Total Dosage & Volume Calculation

Compounding an oral suspension according to these procedures should provide one patient with enough medication for a 5 day course of treatment or 10 day course of prophylaxis.

First, calculate the total volume of oral suspension needed, as determined by the dosage for the patient.

Body Weight	Dose (mg)	Volume per Dose	Treatment Dose (5 days)	Prophylaxis Dose (10 days)
<b>Patients from 2 weeks to less than 1 year of age</b>				
Consult manufacturer/CDC/IDSA recommendations				
<b>Patients older than 1 year based on body weight</b>				
≤ 33 lbs (15 kg)	30 mg	5 mL	5 mL two times daily	5 mL once daily
34 – 51 lbs (16 – 23 kg)	45 mg	7.5 mL	7.5 mL two times daily	7.5 mL once daily
52 – 88 lbs (24 – 40 kg)	60 mg	10 mL	10 mL two times daily	10 mL once daily
≥ 89 lbs (41 kg)	75 mg	12.5 mL	12.5 mL two times daily	12.5 mL once daily

Oseltamivir Dose	Total Volume
15 mg or less	37.5 mL
30 mg	75 mL
45 mg	100 mL
60 mg	125 mL
75 mg	150 mL

## 2 Number of Capsules

Second, determine the number of capsules and amount of vehicle necessary to prepare the total volume of compounded suspension from Step 1:

<b>Total Volume Necessary (from Step 1)</b>	37.5 mL	75 mL	100 mL	125 mL	150 mL
<b>Required number of oseltamivir 75 mg capsules</b>	3 capsules (225 mg)	6 capsules (450 mg)	8 capsules (600 mg)	10 capsules (750 mg)	12 capsules (900 mg)
<b>Required amount of water</b>	2.5 mL	5 mL	7 mL	8 mL	10 mL
<b>Required volume of vehicle</b>	34.5 mL	69 mL	91 mL	115 mL	137 mL
<b>Final Concentration</b>	6 mg/mL				

\*Final concentration of the compounded suspension is the same concentration as the commercially available Tamiflu® suspension.

### 3 Compounding Instructions

Third, follow the compounding procedures below:

1. Add pre-determined amount of water to polyethyleneterephthalate (PET) or glass bottle.
2. Carefully separate the capsule body and cap, and pour contents into the bottle.
3. Gently swirl the contents for 2 minutes to allow wetting of the oseltamivir powder.
4. Slowly pour the pre-determined amount of vehicle into the bottle
5. Close the bottle using a child-resistant cap.
6. Shake well for 30 seconds to completely dissolve active drug and ensure homogenous distribution (Note: the active drug dissolves in solution. A suspension results due to the inert ingredients found in oseltamivir capsules).
7. Put an ancillary label on the bottle indicating "Shake Gently Before Use" prior to administration.
8. Instruct the parent or guardian that any remaining material following completion of therapy must be discarded by either affixing an ancillary label to the bottle or adding to the label instructions.
9. Place an appropriate label according to patient specific instructions and storage conditions described below (Steps 4 & 5)

### 4 Storage Requirements

(Based on studies using approved vehicles and glass or PET bottles)

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

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

### 5 Product Labeling

Place a label on the bottle that includes patient's name, dosing instructions, drug name, and any other information required by state and/or federal regulations.

Note: This procedure results in a **6 mg/mL** suspension (the same concentration as the commercially available oral suspension).

Consider dispensing the suspension with a graduated oral syringe for measuring small amounts. If possible, mark the graduation corresponding to the appropriate dose on the oral syringe. Do NOT use the device dispensed with the commercially-available Tamiflu® suspension.

#### For PHYSICIANS and PHARMACISTS Only: Additional Emergency Options for Administering Oseltamivir:

For patients requiring a 75 mg dose: If a patient cannot swallow the oseltamivir capsules and the patient's dose is 75 mg (one capsule), the capsule can be opened and the contents mixed with sweetened liquids such as chocolate syrup, caramel topping, or corn syrup immediately prior to use.<sup>1</sup>

\*\*For patients requiring a dose less than 75 mg: If an oral suspension cannot be compounded, a temporary emergency measure may be considered. During the initial investigational studies of oseltamivir, the drug was administered dissolved in orange juice.<sup>2</sup> A 75 mg capsule can be opened and mixed in 75 mL (5 tablespoons) of orange juice to make a 1 mg/mL solution. Stir to dissolve. Use an oral syringe to draw up the appropriate dose. For example, 30 mg = 30 mL. Discard any remaining solution immediately. It cannot be stored for later use.

\*Please Note: The 12 mg/mL commercially available product has been discontinued since the original publication of this document in 2009.

\*\*When contacted again in 2018, the manufacturer Genentech could not corroborate the information gathered via personal communication in 2009.