

Compounding of an Oral Suspension from Tamiflu® Capsules



According to the US Food & Drug Administration (FDA), **in the event that oseltamavir (Tamiflu®) is in short supply**, pharmacists may compound a suspension (15 mg/mL) from oseltamivir 75 mg capsules using either of two vehicles: Cherry Syrup (Humco®) or Ora-Sweet® SF (sugar-free) (Paddock Laboratories). Other vehicles have not been specifically studied.

Note: This procedure results in a **15 mg/mL** suspension, which is different from the commercially-available TAMIFLU® for oral suspension, which has a concentration of 12 mg/mL.

Steps for compounding¹ are provided below.

1 Total 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 patient weight.

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

Total Volume Necessary (from Step 1)	30 mL	40 mL	50 mL	60 mL
Required number of oseltamavir 75 mg capsules	6 capsules (450 mg)	8 capsules (600 mg)	10 capsules (750 mg)	12 capsules (900 mg)
Required volume of vehicle	29 mL	38.5 mL	48 mL	57 mL

3 Compounding Instructions

Third, follow the compounding procedures below:

1. Carefully separate the capsule body and cap, and transfer contents into a clean mortar.
2. Triturate the granules into a fine powder.
3. Add one-third (1/3) of the specified amount of vehicle and triturate the powder until a uniform suspension is achieved.
4. Transfer the suspension to an amber glass or amber polyethyleneterephthalate (PET) bottle. A funnel may be used to prevent spilling.
5. Add another one-third (1/3) of the vehicle to the mortar, rinse the pestle and mortar using a triturating motion, and transfer the vehicle to the bottle.
6. Repeat Step 5 (rinsing) with the remaining vehicle.
7. Close the bottle using a child-resistant cap.
8. Shake well 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 oseltamavir tablets).
9. Put an ancillary label on the bottle indicating “Shake Gently Before Use” prior to administration.
10. 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.
11. Place an appropriate expiration date label according to storage conditions described below.

4 Storage Requirements

(Based on studies using approved vehicles and amber 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 or federal regulations. This procedure results in a **15 mg/mL** suspension, which is different from the commercially-available TAMIFLU® for oral suspension, which has a concentration of 12 mg/mL. Dosing instructions are as follows:

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

Note: 5 mL = 1 teaspoon

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 Tamiflu®:

For patients needing a 75 mg dose: If a patient cannot swallow the Tamiflu® capsules and the patient's dose is 75 mg (one capsule), the capsule can be opened and the contents mixed with some chocolate syrup,¹ orange juice,² or applesauce.¹ The mixture should be used immediately.

For patients needing 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 Tamiflu®, the drug was administered dissolved in orange juice.² 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.