

EXTEMPORANEOUS RECIPE FOR OSELTAMIVIR (TAMIFLU®) SUSPENSION¹

A. Preparation of Oseltamivir (Tamiflu®) Suspension from Capsules

Commercially manufactured Oseltamivir (Tamiflu®) for Oral Suspension (12 mg/mL) is the preferred product for pediatric and adult patients who have difficulty swallowing capsules or where lower doses are needed. In the event that Oseltamivir (Tamiflu®) for Oral Suspension is not available, the pharmacist may compound a suspension (15 mg/mL) from Oseltamivir (Tamiflu®) Capsules 75 mg using the vehicle Ora-Sweet SF (sugar-free) (Paddock Laboratories). Other vehicles have not been studied.

First, calculate the Total Volume of an oral suspension needed to be compounded and dispensed for each patient. The Total Volume required is determined by the weight of each patient. Refer to Table 1.

Table 1: Volume of an Oral Suspension (15 mg/mL) needed to be 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

Second, determine the number of capsules and the amount of vehicle (Ora-Sweet SF®) that are needed to prepare the Total Volume (calculated from Table 1: 30 mL, 40 mL, 50 mL, or 60 mL) of compounded oral suspension (15 mg/mL). Refer to Table 2.

¹ Adapted from Tamiflu® Product Monograph, Hoffmann-La Roche, December 2008

Table 2: Number of Oseltamivir (Tamiflu®) 75 mg Capsules and Amount of Vehicle (Ora-Sweet SF®) Needed to Prepare the Total Volume of a Compounded Oral Suspension (15 mg/mL)

Total Volume of Compounded Oral Suspension needed to be Prepared	30 mL	40 mL	50 mL	60 mL
Required number of Oseltamivir (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 Ora-Sweet SF® (Paddock Laboratories)	29 mL	38.5 mL	48 mL	57 mL

Third, follow the procedure below for compounding the oral suspension (15 mg/mL) from Oseltamivir (Tamiflu®) Capsules 75 mg:

- Carefully separate the capsule body and cap and transfer the contents of the required number of the Oseltamivir (Tamiflu®) 75 mg Capsules into a clean mortar.
- Triturate the granules to a fine powder.
- Add one-third (1/3) of the specified amount of vehicle and triturate the powder until a uniform suspension is achieved.
- Transfer the suspension to an amber glass or amber polyethyleneterephthalate (PET) bottle. A funnel may be used to eliminate any spillage.
- Add another one-third (1/3) of the vehicle to the mortar, rinse the pestle and mortar by a triturating motion and transfer the vehicle into the bottle.
- Repeat the rinsing (Step 5) with the remainder of the vehicle.
- Close the bottle using a child-resistant cap.
- Shake well to completely dissolve the active drug and to ensure homogeneous distribution of the dissolved drug in the resulting suspension. (Note: The active drug, oseltamivir phosphate, readily dissolves in the specified vehicle. The suspension is caused by some of the inert ingredients of Oseltamivir (Tamiflu®) Capsules which are insoluble in the vehicle.)
- Put an ancillary label on the bottle indicating "Shake Gently Before Use". [This compounded suspension should be gently shaken prior to administration to minimize the tendency for air entrapment.]
- 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 a statement to the pharmacy label instructions.
- Place an appropriate expiration date label according to storage condition (see below).

¹ Adapted from Tamiflu® Product Monograph, Hoffmann-La Roche, December 2008

B. Storage of the Pharmacy-Compounded Suspension

Compounded with Ora-Sweet[®] SF: Stable for 5 weeks (35 days) when stored at 25°C.

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

Place a pharmacy label on the bottle that includes the patient's name, dosing instructions, and drug name and any other required information to be in compliance with all Provincial and Federal Pharmacy Regulations. **Refer to Table 3 for the proper dosing instructions.**

Note: This compounding procedure results in a 15 mg/mL suspension, which is different from the commercially available Oseltamivir (Tamiflu[®]) for Oral Suspension, which has a concentration of 12 mg/mL.

Table 3: Dosing Chart for Pharmacy-Compounded Suspension from Oseltamivir (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

Note: 1 teaspoon = 5 mL

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

¹ Adapted from Tamiflu[®] Product Monograph, Hoffmann-La Roche, December 2008