

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 polyethylenetere phthalate (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-SweetSF 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).
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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 polyethylenetere phthalate (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.

674 **HOW SUPPLIED**

675 **TAMIFLU Capsules**

676 30-mg capsules (30 mg free base equivalent of the phosphate salt): light yellow hard
677 gelatin capsules. "ROCHE" is printed in blue ink on the light yellow body and "30 mg" is
678 printed in blue ink on the light yellow cap. Available in blister packages of 10 (NDC
679 0004-0802-85).

680 45-mg capsules (45 mg free base equivalent of the phosphate salt): grey hard gelatin
681 capsules. "ROCHE" is printed in blue ink on the grey body and "45 mg" is printed in blue
682 ink on the grey cap. Available in blister packages of 10 (NDC 0004-0801-85).

683 75-mg capsules (75 mg free base equivalent of the phosphate salt): grey/light yellow hard
684 gelatin capsules. "ROCHE" is printed in blue ink on the grey body and "75 mg" is printed
685 in blue ink on the light yellow cap. Available in blister packages of 10 (NDC 0004-0800-
686 85).

687 **Storage**

688 Store the capsules at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See
689 USP Controlled Room Temperature]

690 **TAMIFLU for Oral Suspension**

691 Supplied as a white powder blend for constitution to a white tutti-frutti-flavored
692 suspension. Available in glass bottles containing approximately 33 mL of suspension
693 after constitution. Each bottle delivers 25 mL of suspension equivalent to 300 mg
694 oseltamivir base. Each bottle is supplied with a bottle adapter and 1 oral dispenser (NDC
695 0004-0810-95).

696 **Storage**

697 Store dry powder at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See
698 USP Controlled Room Temperature]

699 Store constituted suspension under refrigeration at 2° to 8°C (36° to 46°F). Do not freeze.

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701 Humco® is a registered trademark of Humco Holding Group, Inc.

702 Ora-Sweet® SF is a registered trademark of Paddock Laboratories

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