

Dosage and administration in adults and adolescents (aged ≥ 13 years)



Adult dosing schedule

Adult Dosing (≥ 13 years)	Dosage
Treatment	75 mg twice daily for 5 days
Prophylaxis	75 mg once daily for at least 10 days
Renal Impairment Dosing* creatinine clearance between 10 mL/min and 30 mL/min	Dosage
Treatment	75 mg once daily for 5 days
Prophylaxis	75 mg every other day or 30 mg oral suspension once daily

* No recommended dosing regimens are available for patients with end-stage renal disease undergoing routine hemodialysis or continuous peritoneal dialysis treatment.

- Treatment should begin within 2 days of symptom onset
- Prophylaxis therapy should begin within 2 days of exposure to an infected individual
 - The duration of protection lasts for as long as dosing is continued.

Safety and efficacy have been demonstrated for up to 6 weeks in immunocompetent patients. Please see accompanying full [Prescribing Information](#), including **Boxed WARNINGS**, and inside for additional important safety information.



Please see accompanying full Prescribing Information.

Indications and Limitations of Use

TAMIFLU is indicated in patients 1 year and older for the treatment of uncomplicated influenza caused by viruses types A and B who have been symptomatic for no more than 2 days and for the prophylaxis of influenza.

Efficacy of TAMIFLU in patients who begin treatment after 48 hours of symptoms has not been established.

TAMIFLU is not a substitute for early and annual vaccination as recommended by the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP).

There is no evidence for efficacy of TAMIFLU in any illness caused by agents other than influenza viruses Types A and B.

Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefits of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use TAMIFLU.

Important Safety Information

TAMIFLU is contraindicated in patients who have had severe allergic reactions such as anaphylaxis or serious skin reactions such as toxic epidermal necrolysis, Stevens-Johnson syndrome, or erythema multiforme to any component of TAMIFLU. Cases of these events have been reported in postmarketing experience with TAMIFLU. Tamiflu should be stopped and appropriate treatment instituted if an allergic-like reaction occurs or is suspected.

There have been postmarketing reports of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving TAMIFLU. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of TAMIFLU to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior. If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient.

Serious bacterial infections may begin with influenza-like symptoms or may co-exist with or occur as complications during the course of influenza. TAMIFLU has not been shown to prevent such complications.

Efficacy in subjects with chronic cardiac and/or respiratory disease or in immunocompromised patients has not been established. No information is available regarding treatment of influenza in patients at imminent risk of requiring hospitalization.

The concurrent use of TAMIFLU with live attenuated influenza vaccine (LAIV) intranasal has not been evaluated. However, because of the potential for interference between these products, LAIV should not be administered within 2 weeks before or 48 hours after administration of TAMIFLU, unless medically indicated.

Adverse events that occurred more frequently in patients treated with TAMIFLU than in patients taking placebo and occurred in ≥2% of patients were (TAMIFLU%, placebo %):

- Treatment in adults – nausea (10%, 6%), vomiting (9%, 3%), bronchitis (2%, 2%)
- Treatment in pediatrics – vomiting (15%, 9%), abdominal pain (5%, 4%), epistaxis (3%, 3%), ear disorder (2%, 1%)
- Prophylaxis of adults – headache (18%, 18%), nausea (7%, 3%), diarrhea (3%, 2%), vomiting (2%, 1%), abdominal pain (2%, 1%)
- Prophylaxis of pediatrics – vomiting (10%, 2%), abdominal pain (3%, 0%), nausea (4%, 1%)

Please see accompanying full [Prescribing Information](#), including **Boxed WARNINGS**, and inside for additional important safety information.



Dosage and administration in pediatric patients (aged 1-12 years)



Pediatric dosing guidelines

- Available as an oral suspension
 - TAMIFLU for oral suspension (6 mg/mL) should be used within 17 days of preparation when stored under refrigeration or within 10 days if stored at controlled room temperature (25°C/77°F)
- May be taken with or without food
- When taken with food, tolerability may be enhanced in some patients

PEDIATRIC TREATMENT

- TAMIFLU is not indicated for treatment of influenza in pediatric patients younger than 1 year
- Treatment should begin within 2 days of symptom onset

PEDIATRIC POSTEXPOSURE PROPHYLAXIS

- The safety and efficacy of TAMIFLU for prophylaxis of influenza in pediatric patients younger than 1 year have not been established
- Prophylaxis in pediatric patients following close contact with an infected individual is recommended for 10 days
- Prophylaxis therapy should begin within 2 days of exposure

Please see accompanying full Prescribing Information.
Please see Important Safety Information on reverse side.

Dosing and Administration

TAMIFLU may be taken with or without food. However, when taken with food, tolerability may be enhanced in some patients. The recommended oral treatment and prophylaxis dose of TAMIFLU for patients 1 year of age and older is shown in the table below.

Treatment and Prophylaxis Dosing of Oral TAMIFLU for Influenza For Patients 1 Year of Age and Older Based on Body Weight						
Weight (kg)	Weight (lbs)	Treatment Dosing for 5 days	Prophylaxis Dosing for 10 days	Volume of Oral Suspension (6 mg/mL) for each Dose*	Number of Bottles of Oral Suspension to Dispense	Number of Capsules and Strength to Dispense
15 kg or less	33 lbs or less	30 mg twice daily	30 mg once daily	5 mL	1 bottle	10 Capsules, 30 mg
16 kg thru 23 kg	34 lbs thru 51 lbs	45 mg twice daily	45 mg once daily	7.5 mL	2 bottles	10 Capsules, 45 mg
24 kg thru 40 kg	52 lbs thru 88 lbs	60 mg twice daily	60 mg once daily	10 mL	2 bottles	20 Capsules, 30 mg
41 kg or more	89 lbs or more	75 mg twice daily	75 mg once daily	12.5 mL†	3 bottles	10 Capsules, 75 mg

* A 10 mL oral dosing dispenser is provided with the oral suspension. In the event that the dispenser provided is lost or damaged, another dosing dispenser may be used to deliver the volumes.

† Delivery of this TAMIFLU for Oral Suspension dose requires administering 10 mL followed by another 2.5 mL.

Please see accompanying full Prescribing Information, including **Boxed WARNINGS**, and inside for additional important safety information.

The prophylaxis duration of protection lasts for as long as dosing is continued.

- For prophylaxis in pediatric patients during a community outbreak of influenza, dosing may be continued for up to 6 weeks.

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