



dosage and administration—

- adults and adolescents (≥13 years old)

treat. prevent. protect. **Tamiflu**[®]
oseltamivir phosphate

Roche: Dedicated to Improving Influenza Management

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TREATMENT

Easy to take, easy to prescribe

- One 75-mg capsule twice daily for 5 days
—In patients with creatinine clearance between 10 mL/min and 30 mL/min, one 75-mg capsule once daily for 5 days*
- Treatment should begin within 2 days of symptom onset
- May be taken with or without food
- When taken with food, tolerability may be enhanced in some patients

PROPHYLAXIS

For postexposure prophylaxis

- One 75-mg capsule once daily for at least 10 days
—In patients with creatinine clearance between 10 mL/min and 30 mL/min, one 75-mg capsule every other day or 30-mg oral suspension once daily*
- Administration should begin within 2 days of exposure to an infected close contact

For seasonal prophylaxis

- One 75-mg capsule once daily during a community outbreak
—In patients with creatinine clearance between 10 mL/min and 30 mL/min, one 75-mg capsule every other day or 30-mg oral suspension once daily*
- Safety and efficacy have been demonstrated for up to 6 weeks
- Duration of protection lasts for as long as dosing is continued

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

INDICATIONS

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

TAMIFLU is also indicated for the prophylaxis of influenza in patients 1 year and older.

TAMIFLU is not a substitute for early and annual vaccination.

Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use TAMIFLU.

SAFETY INFORMATION

There is no evidence for efficacy against any illness caused by agents other than influenza types A and B.

Treatment efficacy in subjects with chronic cardiac and/or respiratory disease has not been established. No difference in the incidence of complications was observed between the treatment and placebo groups in this population.

No information is available regarding treatment of influenza in patients at imminent risk of requiring hospitalization. Efficacy of TAMIFLU has not been established in immunocompromised patients. Safety and efficacy of repeated treatment or prophylaxis courses have not been studied.

Influenza can be associated with a variety of neurologic and behavioral symptoms, which can include events such as hallucinations, delirium and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease. There have been postmarketing reports (mostly from Japan) of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving TAMIFLU. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made but they appear to be uncommon based on TAMIFLU usage data. 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.

In postmarketing experience, rare cases of anaphylaxis and serious skin reactions, including toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme, have been reported with TAMIFLU.

The most common adverse events reported >1% of patients treated with TAMIFLU and more commonly than in patients treated with placebo are:

- Treatment of adult and pediatric patients – nausea, vomiting.
- Prophylaxis of adult and pediatric patients – nausea, vomiting, abdominal pain.

Vaccination is considered the first line of defense against influenza.

Please see accompanying complete Prescribing Information.



dosage and administration—

- pediatric patients (≥1 year old)

PEDIATRIC INDICATIONS

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

TAMIFLU is also indicated for the prophylaxis of influenza in patients 1 year and older.

TAMIFLU is not a substitute for early and annual vaccination.

Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use TAMIFLU.

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

EASY TO TAKE, EASY TO PRESCRIBE

- Available as an oral suspension
 - Requires refrigeration after constitution
 - Please discard TAMIFLU for Oral Suspension 10 days after constitution date
- May be taken with or without food
- When taken with food, tolerability may be enhanced in some patients

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 patients aged 1 to 12 years has not been evaluated for longer than 10 days' duration
- Prophylaxis therapy should begin within 2 days of exposure

The recommended dose of TAMIFLU for Oral Suspension* for pediatric patients aged 1 year and older (or adults unable to swallow a capsule) for treatment and prophylaxis is as follows:

Body Weight lbs (kg)	TREATMENT Recommended Dose for 5 Days	PROPHYLAXIS Recommended Dose for 10 Days	Number of Bottles Needed to Deliver Recommended Dose
≤33 lbs (≤15 kg)	30 mg twice daily	30 mg once daily	1
>33 lbs-51 lbs (>15 kg-23 kg)	45 mg twice daily	45 mg once daily	2
>51 lbs-88 lbs (>23 kg-40 kg)	60 mg twice daily	60 mg once daily	2
>88 lbs (>40 kg)	75 mg twice daily	75 mg once daily	3

Children >88 lbs (>40 kg) can be prescribed TAMIFLU capsules.

*Note: TAMIFLU for Oral Suspension should be prescribed, prepared, and dispensed in milligrams. It is recommended that patients use the provided oral dosing dispenser, with 30-mg, 45-mg and 60-mg graduations (75-mg dose can be measured using a combination of 30 mg and 45 mg). If the dispenser provided is lost or damaged, another dosing syringe/device may be used to deliver the following volumes: 2.5 mL (1/2 tsp) for children ≤15 kg; 3.8 mL (3/4 tsp) for >15 to 23 kg; 5.0 mL (1 tsp) for >23 to 40 kg; and 6.2 mL (1-1/4 tsp) for >40 kg.

NOTE: SHAKE TAMIFLU ORAL SUSPENSION WELL BEFORE EACH USE.



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