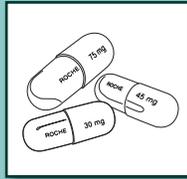


# TAMIFLU: flexible formulations for patients 1 year and older



- TAMIFLU capsules are available in strengths of:
  - 30 mg
  - 45 mg
  - 75 mg
- All capsules, regardless of strength, are supplied in packages of 10

## Recommended TAMIFLU dosing for patients $\geq 1$ year

BODY WEIGHT	DOSE AND NUMBER OF CAPSULES
<b>TREATMENT DOSING SCHEDULE (5 DAYS)</b>	
$\leq 33$ lbs ( $\leq 15$ kg)	30 mg: 1 x 30 mg <b>twice a day</b>
>33 lbs-51 lbs (>15 kg-23 kg)	45 mg: 1 x 45 mg <b>twice a day</b>
>51-88 lbs (>23 kg-40 kg)	60 mg: 2 x 30 mg <b>twice a day</b>
>88 lbs (>40 kg)	75 mg: 1 x 75 mg* <b>twice a day</b>
<b>POSTEXPOSURE PROPHYLAXIS† (10 DAYS)</b>	
$\leq 33$ lbs ( $\leq 15$ kg)	30 mg: 1 x 30 mg <b>once a day</b>
>33 lbs-51 lbs (>15 kg-23 kg)	45 mg: 1 x 45 mg <b>once a day</b>
>51-88 lbs (>23 kg-40 kg)	60 mg: 2 x 30 mg <b>once a day</b>
>88 lbs (>40 kg)	75 mg: 1 x 75 mg* <b>once a day</b>

\*A combination of one TAMIFLU 30 mg and one TAMIFLU 45 mg capsule may be substituted for one TAMIFLU 75 mg capsule.

†The duration of protection is as long as dosing is continued.



- TAMIFLU 12 mg/mL oral suspension (fruit flavored) is available for children  $\geq 1$  year of age and adults who cannot swallow capsules
- If TAMIFLU oral suspension is not available, pharmacists may compound a suspension (15 mg/mL) from TAMIFLU 75 mg capsules using either Humco® Cherry Syrup or Ora-Sweet® SF for individual patients
- If the pharmacy is unable to provide compounded suspension, healthcare providers can direct patients or caregivers to mix the contents of TAMIFLU capsules with sweetened liquids (eg, regular or sugar-free chocolate syrup)



Please see attached full Prescribing Information.

Please see reverse side for Indications and Important Safety Information.

Ask your Roche representative for the TAMIFLU mixing instructions sheet for patients or caregivers.



Pharmaceuticals

For further information about mixing and dosing TAMIFLU, please visit [www.TAMIFLU.com](http://www.TAMIFLU.com)

**Tamiflu**<sup>®</sup>  
oseltamivir phosphate

## 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 as recommended by the Centers for Disease Control's Advisory Committee on Immunization Practices (ACIP).

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

Vaccination is considered the first line of defense against influenza.

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.

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

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.

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.

Adverse events that occurred more frequently in patients treated with TAMIFLU than in patients taking placebo and occurred in  $\geq 2\%$  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%)



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SPACE FOR P.I.

  
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