



Patient Information

TAMIFLU®

(oseltamivir phosphate)

R_x only

This leaflet contains important information about TAMIFLU (TAM-ih-flew). Read it well before you begin treatment. This information does not take the place of talking with your healthcare professional about your medical condition or your treatment. This leaflet does not list all the benefits and risks of TAMIFLU. If you have any questions about TAMIFLU, ask your healthcare professional. Only your healthcare professional can determine if TAMIFLU is right for you.

What is TAMIFLU?

TAMIFLU attacks the influenza virus and stops it from spreading inside your body. TAMIFLU treats flu at its source, by attacking the virus that causes the flu, rather than simply masking symptoms.

TAMIFLU is for treating adults and children age 1 and older with the flu whose flu symptoms started within the last day or two. TAMIFLU can also reduce the chance of getting the flu in people age 1 and older who have a higher chance of getting the flu because they spend time with someone who has the flu. TAMIFLU can also reduce the chance of getting the flu if there is a flu outbreak in the community.

What is “Flu”?

“The flu” is an infection caused by the influenza virus. Flu symptoms include fever (usually 100°F to 103°F in adults, and sometimes higher in children) and problems such as cough, sore throat, runny or stuffy nose, headaches, muscle aches, fever, and extreme tiredness. Many people use the term “flu” to mean any combination of these symptoms, such as the common cold, but true influenza infection is often worse and may last longer than a cold.

Flu outbreaks happen about once a year, usually in the winter, when the influenza virus spreads widely in the community. Outside of those outbreaks, only a very tiny number of respiratory infections are caused by the influenza virus.

Should I get a flu shot?

TAMIFLU is not a substitute for a flu vaccination. You should continue to get a flu vaccination every year, according to your healthcare professional’s advice.

34 **Who should not take TAMIFLU?**

35 Do not take TAMIFLU if you are allergic to the main ingredient, oseltamivir phosphate,
36 or to any other ingredients of TAMIFLU. Before starting treatment, make sure your
37 healthcare professional knows if you take any other medicines, or are pregnant, planning
38 to become pregnant, or breastfeeding. TAMIFLU is normally not recommended for use
39 during pregnancy or nursing, as the effects on the unborn child or nursing infant are
40 unknown. TAMIFLU is not recommended for use in children younger than 1 year of age.

41 Tell your healthcare professional if you have any type of kidney disease, heart disease,
42 respiratory disease, or any serious health condition.

43 **How should I take TAMIFLU?**

44 It is important that you begin your treatment with TAMIFLU as soon as possible from the
45 first appearance of your flu symptoms or soon after you are exposed to the flu. If you feel
46 worse or develop new symptoms during treatment with TAMIFLU, or if your flu
47 symptoms do not start to get better, you should contact your healthcare professional.

48 If you have the flu: Take TAMIFLU twice a day for 5 days, once in the morning and
49 once in the evening. You should complete the entire treatment of 10 doses (capsules or
50 liquid), even if you feel better.

51 To prevent the flu: If someone in your home has the flu, take TAMIFLU once a day for
52 10 days or for as long as prescribed. You can take TAMIFLU for up to 6 weeks if you are
53 exposed to the flu because of an outbreak in your community. Follow your healthcare
54 professional's advice on how long to take TAMIFLU.

55 TAMIFLU has not been studied in children 1 to 12 years of age for preventing flu during
56 an outbreak in your community or for use for more than 10 days.

57 You can take TAMIFLU with food or without food. There is less chance of stomach
58 upset if you take it with a light snack, milk, or a meal.

59 If you are taking TAMIFLU liquid, your pharmacist will give you a dosing dispenser
60 marked with three possible doses. Follow your healthcare professional's instructions on
61 which dose to take or how to combine them for the proper dose for you. In order to be
62 sure you receive the proper dose, it is important that you use the dispenser provided.
63 Review the instructions below on how to use the dispenser and ask your pharmacist if
64 you have any questions. If you lose or damage the dispenser and cannot use it, contact
65 your healthcare professional or pharmacist for advice on the proper dose.

66 If you forget to take your medicine, take the missed dose as soon as you remember,
67 except if it is 2 hours or less before your next dose. Then continue to take TAMIFLU at
68 the usual times. Do not take 2 doses at a time to make up for a missed dose. If you miss
69 several doses, tell your healthcare professional and follow the advice given to you.

70 **What are the possible side effects of TAMIFLU?**

71 The most common side effects of TAMIFLU are nausea and vomiting. These are usually
72 mild to moderate. They usually happen in the first 2 days of treatment. Taking TAMIFLU
73 with food may reduce the chance of getting these side effects.

74 If you develop an allergic reaction or severe rash, stop taking TAMIFLU and contact
75 your healthcare professional.

76 People with the flu, particularly children, may be at an increased risk of self-injury and
77 confusion shortly after taking TAMIFLU and should be closely monitored for signs of
78 unusual behavior. A healthcare professional should be contacted immediately if the
79 patient taking TAMIFLU shows any signs of unusual behavior.

80 Before taking TAMIFLU, please let your healthcare provider know if you have received
81 nasally administered influenza virus vaccine during the past two weeks.

82 If you notice any side effects not mentioned in this leaflet, or if you have any concerns
83 about the side effects you get, tell your healthcare professional.

84 **How and where should I store TAMIFLU?**

85 TAMIFLU capsules should be stored at room temperature below 77°F (25°C) and kept in
86 a dry place. Keep this medication out of reach of children.

87 TAMIFLU suspension should be stored under refrigeration at 36° to 46°F (2° to 8°C). Do
88 not freeze.

89 **General advice about prescription medicines:**

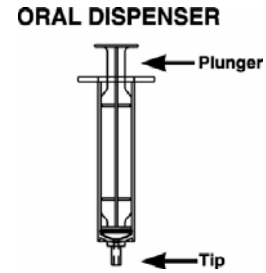
90 Medicines are sometimes prescribed for conditions that are not mentioned in patient
91 information leaflets. Do not use TAMIFLU for a condition for which it was not
92 prescribed. Do not give TAMIFLU to other people, even if they have the same symptoms
93 you have. It may not be right for them.

94 This leaflet summarizes the most important information about TAMIFLU. If you would
95 like more information, talk with your healthcare professional. You can ask your
96 pharmacist or healthcare professional for information about TAMIFLU that is written for
97 health professionals.

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99 **DOSING INSTRUCTIONS FOR PATIENTS:**

100 **Please follow instructions carefully to ensure proper dosing of the oral suspension.**



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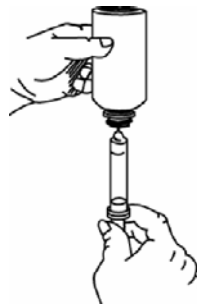
102 • Shake closed bottle well for about 5 seconds before each use.

103 • Remove child-resistant cap.

104 • Before inserting the tip of the oral dispenser into bottle adapter, push the plunger
 105 completely down toward the tip of the oral dispenser. Insert tip firmly into opening of
 106 the bottle adapter.

107 • Turn the entire unit (bottle and oral dispenser) upside down.

108 • Pull the plunger out slowly until the desired amount of medication is withdrawn into
 109 the oral dispenser (see figure). The 75 mg dose is obtained by filling the dispenser
 110 twice, once to the 30 mg graduation, and a second fill to the 45 mg graduation.



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112 • Turn the entire unit right side up and remove the oral dispenser slowly from the
 113 bottle.

114 • Dispense directly into mouth. Do not mix with any liquid prior to dispensing.

115 • Close bottle with child-resistant cap after each use.

116 • Disassemble oral dispenser, rinse under running tap water and air dry prior to next
 117 use.

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