

5. TAMIFLU[®] (oseltamivir phosphate) Supply and Ordering



Will there be an adequate supply of TAMIFLU?

Ready to meet your TAMIFLU needs

To date, Roche has been able to meet the increasing global demand for TAMIFLU. While supply during a pandemic is not certain, there is supply currently available for organizations.

Recently, Roche announced a significant expansion of its global manufacturing network for the production of TAMIFLU. By the end of 2006, Roche will have the capacity to produce up to 400 million treatments annually, an increase of 100 million. The enhanced capacity will be achieved through the addition of external production contractors identified over the past few months as well as the expansion of facilities owned by Roche.⁴⁶

Expanded global production network⁴⁶

The Roche global network for the manufacture of TAMIFLU will include several Roche sites and more than 15 external contractors located in 9 different countries around the world. These production contractors have been selected primarily on the basis of their ability to produce substantial quantities of intermediates and finished materials in accordance with the Roche quality standards within a relatively short time frame.

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Will there be an adequate supply of TAMIFLU? (cont'd)

Following our open invitation to third parties last year, we have now identified partners who will allow us to expand the global TAMIFLU capacity to as much as 400 million treatments annually by the end of this year. Of course, the rate at which this capacity is utilized will depend in large part on the future order flow from governments around the world. We are now ahead of demand in meeting the manufacturing challenge, but as a research-based company, our role goes beyond this.

—William M. Burns, CEO Roche Pharma Division⁴⁶

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How much TAMIFLU is the US government stockpiling?

Strategic national stockpile⁴⁷

The CDC's Strategic National Stockpile (SNS) has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (eg, terrorist attack, flu outbreak or weather disaster) severe enough to cause local supplies to run out. Once federal and local authorities agree that the SNS is needed, medicines will be delivered to any state in the United States within 12 hours. Each state has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible.

Antiviral stockpiling – federal government⁴⁸

United States Department of Health and Human Services Secretary Mike Leavitt recently announced additional purchases of antiviral drugs that could be used in the event of a potential influenza pandemic. With these purchases, the SNS will have a total of 26 million treatment courses of antiviral drugs for distribution to the states when an influenza pandemic is deemed to be imminent. "Our ultimate goal is to stockpile sufficient quantities of antiviral drugs to treat 25 percent of the US population," Secretary Leavitt said.

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How much TAMIFLU is the US government stockpiling? (cont'd)

Antiviral stockpiling – state and local government

A pandemic occurs in many localities almost simultaneously. Because of this, much of the planning for a pandemic must be the responsibility of state and local governments. The Department of Health and Human Services (HHS) is stockpiling antivirals and is allocating them to states based on population. Purchases in FY2006 will bring the nation's stockpile of antivirals to 20 million courses by the end of this year. (A course is the supply needed to treat one person.) With anticipated FY2007 funding, HHS plans to order an additional 24 million courses, which will likely be delivered in 2008. An additional 31 million courses (FY2006) are available for state purchase, with HHS providing a 25 percent subsidy. State governors have been asked to notify HHS of their plans to purchase their allocated antivirals by July 1, 2006.

To view state allocations of antivirals, please visit:
<http://www.pandemicflu.gov/state/antivirals.html>

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How can my organization obtain TAMIFLU for pandemic preparedness?

Antivirals are an important component of a detailed corporate pandemic response plan. Roche has developed this document as a tool to assist all organizations interested in obtaining TAMIFLU in the event of a pandemic.

We understand that organizations interested in TAMIFLU acquisition vary widely in terms of their experience in pandemic planning and resources available to allocate to this endeavor. What this tool outlines, therefore, is a *general* process for acquiring TAMIFLU that will need to be tailored to your organization's needs based on its size, facilities, number of sites, geographic distribution of employees, availability of employee health services and other factors. For all organizations, the process begins with assessing your needs for TAMIFLU, and encompasses product ordering and storage, physician consultations and generation of prescriptions, employee education and product distribution.

The process can be completed in one of two primary ways:

1. Using a third-party facilitator* (skilled and staffed to coordinate an antiviral program on your company's behalf)
2. Internally coordinating the acquisition of TAMIFLU

*For guidance on selecting a facilitator, please see page 54, Table 1.

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How can my organization obtain TAMIFLU for pandemic preparedness? (cont'd)

After reviewing this tool, you may decide that using a third-party facilitator is the most appropriate option for your organization. The benefits of this option are the facilitator's experience, skill, resources and single point of contact for your organization to complete the process from start to finish. Or, you may feel that your organization can internally coordinate the acquisition of TAMIFLU, in which case you will follow the 7-step process described.

Regardless of the course you choose, our goal is to assist you in meeting your objective: acquisition of antivirals as part of your pandemic response plan.

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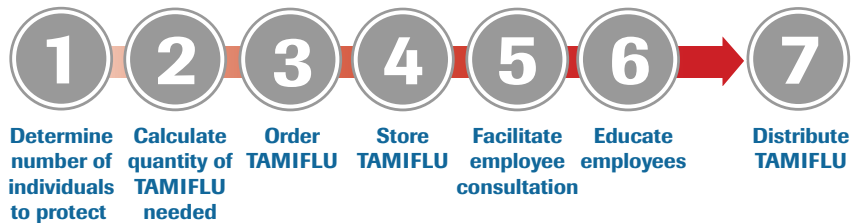
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Seven-step process for acquisition of TAMIFLU

At Roche, we developed and are currently implementing a 7-step process to provide TAMIFLU to our employees. This supports our own corporate mission during a pandemic, which is to:

- Protect our employees
- Ensure continued manufacturing of important medications during a pandemic

Seven-step process



Please see the following pages for details on each of these steps. In some cases, you will be referred to the accompanying TAMIFLU and Flu Pandemic background information.

NOTES:

- The steps need not be completed sequentially
- Choices made at one step may impact those made at others
- Consider engaging a third-party facilitator to coordinate this process if your organization does not have the resources to allocate to this endeavor

Roche Contact Information

If you have general questions regarding this Pandemic Planning Toolkit or require assistance in coordinating an antiviral program for your employees, please contact Roche:

Phone: Pandemic Planning Hotline: (800) 551-2231

E-mail: Nutley.TAMIFLU_Inquiry@Roche.com

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Step 1 Determine the number of individuals to protect

To determine which and how many individuals to protect, your organization must first clearly establish its mission or objectives during a pandemic. NOTE: Your corporate mission during a pandemic will almost certainly differ from your standard operating mission.

A retail manufacturer may have dual objectives during a pandemic:

- Protect its employees
- Continue to produce vital products for its customer base

Use the mission/objectives during a pandemic to determine the number of individuals you will need to protect.

The following checklist should prove helpful in this determination.

■ Establish mission/objectives in a pandemic

Obtain agreement from senior management on the organization's mission during a pandemic (business continuity, employee protection, both, other)

■ If business continuity is the sole objective:

- Identify which products and/or services must continue during a pandemic to fulfill the corporate mission
- Specify the critical activities that are required for those products and/or services
- Identify job roles that are essential to support those critical activities
- Distinguish job roles that can be performed only on-site from those that can be performed off-site
- Identify employees who fill the "essential" roles and employees who can provide back-up
- Identify functional areas that may need an increase in the number of employees (eg, security)

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- **If business continuity and employee protection are *dual objectives*, determine which employees to cover beyond the “essential employees.”**

Consider internal and external groups you need to protect.

The following internal groups may be considered for coverage:

- Senior management
- Employees who interact with the public
- Employees at headquarters locations
- Percentage of all employees
- All employees

The following external groups may be considered for coverage:

- Key contractors and suppliers
- Family members of employees
- Members of the surrounding community

- **Estimate the number of new employees who may need to be hired to maintain business continuity.**
- **Arrive at the total number of individuals your organization will need to protect:**

Total number to protect = [# internal] + [# external] + [# new hires]

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Step 2 Calculate quantity of TAMIFLU needed

Once your organization has determined the number of individuals to protect, it must decide *for what purpose TAMIFLU should be used*. Follow these steps to assist you in calculating an order quantity for your organization.

■ **STEP 2A: Determine course of therapy: Treatment vs Prevention**

- Treatment:** Adults (13 years and older) should take 75 mg twice daily for 5 days for treatment. This equates to 1 pack of capsules
- Prevention:** Adults (13 years and older) should take 75 mg once daily for 10 days following known or suspected exposure, or 75 mg once daily for up to 6 weeks when influenza is known to be circulating in the community

NOTE: For use in children aged 1-12 years (eg, when purchased for family members of employees), see dosing guidelines provided in the accompanying complete Prescribing Information.

■ **STEP 2B: Determine proper dosing (refer to Section 4: TAMIFLU Background)**

- Dosage may vary for seasonal vs pandemic flu depending on the strain of influenza that is circulating
- Current recommendations for pandemic dosing are consistent with treatment and prevention dosage for seasonal influenza (refer to www.who.org for current guidance)

■ **STEP 2C: Assess how many pandemic waves to cover (refer to Section 2: Flu Pandemic Background)**

- Past pandemics have spread globally in two and sometimes three waves
- The organization may want to consider purchasing antivirals that protect employees for more than one wave of a pandemic

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■ **STEP 2D: Calculate the order quantity**

Determine:

- a. The total number of individuals to protect from Step 1
- b. The number of courses of therapy per individual (1 treatment course = 1 pack of 10 capsules; 1 prevention course = 1 pack of 10 capsules)
- c. The dosage level (eg, multiply by 1 for seasonal dosage level or multiply by 2 if you are administering double the seasonal dosage level)
- d. The number of waves (multiply by 1 if covering for only one wave or multiply by 2 if you are covering for two waves, etc.)

$$\text{TAMIFLU Order Quantity (number of packs)} = a \times b \times c \times d$$

Sample calculation:

Company XYZ employs 1,000 individuals, and employees have on average 3 immediate family members (4,000 individuals).

Company XYZ is covering 40 percent of this population:

$$a = 40 \text{ percent} \times 4,000 \text{ individuals} = 1,600$$

The company assumes that each individual will be provided 2 treatment courses (2 packs) and 2 prevention courses (2 packs):

$$b = 4$$

The company assumes that the seasonal dosage will be used:

$$c = 1$$

The company assumes that there will be two waves of a pandemic:

$$d = 2$$

$$\text{TAMIFLU Order Quantity (number of packs)} =$$

$$a \times b \times c \times d = 1,600 \times 4 \times 1 \times 2 = 12,800$$

ORDER QUANTITY = 12,800 packs of TAMIFLU

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Step 3 Order TAMIFLU for your organization

Now that you have identified the *quantity* of TAMIFLU needed, you will need to *order* TAMIFLU for your organization. You may place an order for TAMIFLU from a number of entities (see Table 1 below).

TABLE 1. Entities through which you may order TAMIFLU*

Entity	Description	How to identify/contact
Pharmaceutical wholesalers	Buy product directly from manufacturers and resell to retail customers	http://www.rocheusa.com/programs/Authorized_Distributors.pdf
Specialty distributors	Buy product directly from manufacturers and resell to smaller groups of customers. Able to provide specialized services to its customer base	http://www.rocheusa.com/programs/Authorized_Distributors.pdf
Pharmacy benefit managers (PBMs)	Process pharmaceutical claims for pharmacies and fulfill pharmaceutical prescription orders via mail-order service. Some PBMs will serve as a third-party facilitator (ie, handle transactions from order processing to product distribution)	A partial list of PBMs includes Caremark: www.caremark.com ; Express Scripts: www.express-scripts.com ; Medco: www.medco.com
Corporate healthcare providers (CHPs)	Offer on-site health services that deliver primary care, occupational health and wellness programs for corporate employees. Some CHPs will serve as a third-party facilitator (ie, handle transactions from order processing to product distribution)	A partial list of CHPs includes Affiliated Physicians: www.affiliatedphysicians.net ; CHD Meridian: www.chdmeridian.com ; Comprehensive Health Solutions: www.chsmedical.com
Clinics with a dispensing license	Often can provide a broad range of primary and specialty medical care services for the local community. Clinic must be registered to dispense medicines	Please consult your local Chamber of Commerce
Physicians with a dispensing license	Local primary care physicians who are registered to dispense medicines	Please consult your local Chamber of Commerce

*Entities include, but are not limited to, those presented here.

The following checklist of considerations and coincident questions will help you determine the appropriate entity through which your organization should order TAMIFLU. Please remember that TAMIFLU is a prescription medication; therefore, each individual will need a prescription prior to receiving the drug.

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■ Review capabilities for employee healthcare delivery

Use the questions below to assist in your decision making.

1. Does your organization have an on-site clinic with the ability to dispense prescription drugs?
2. Does your organization have a relationship (eg, employee wellness programs) with a local clinic or physician group?
3. Does your organization meet the capacity and other storage criteria to house the quantity of TAMIFLU you are planning to order? (See Step 4: *Store TAMIFLU for your organization*)

Enter your YES or NO response to each question here:

Q1	Q2	Q3

The following table will assist you in your decision making based on your responses to the previous questions.

Q1	Q2	Q3	SOLUTION
NO	NO	NO	Your organization should consider using a third-party facilitator such as a pharmacy benefit manager (PBM) or a corporate healthcare provider (CHP).
NO	NO	YES	
NO	YES	YES	Your organization should consider ordering product through a clinic or physician's office.
YES	NO	NO	Your organization should consider ordering product through a wholesaler or specialty distributor; however, you must first determine whether these entities can store product on your company's behalf.
NO	YES	NO	Your organization should consider ordering product through a clinic or physician's office; however, you must first determine which of these entities can store product on your company's behalf. If the clinic or physician's office is unable to order or store product on your company's behalf, the organization can use a third-party facilitator such as a PBM or a CHP.
YES	YES	NO	Your organization should consider ordering product through a wholesaler, specialty distributor, clinic or physician's office; however, you must first determine which of these entities can store product on your company's behalf.
YES	NO	YES	Your organization should consider ordering product through either a wholesaler or distributor.
YES	YES	YES	Your organization should consider ordering product through a wholesaler, specialty distributor, clinic or physician's office.

NOTE: In every scenario, organizations preferring a single point of contact should consider a third-party facilitator.

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■ Determine preference for TAMIFLU shipping

Decide if your organization wants to receive product as:

- Single shipment: May be best for smaller orders or for an individual receiving location
- Staggered shipments: May be best for larger orders or for multiple receiving locations

■ Discuss key issues with candidate entities

Identify a short list of candidate entities to contact and, at a minimum, discuss the following issues:

- Order terms/pricing
- Delivery scheduling
- Competitive bidding

■ Roche Contact Information

If you have general questions regarding this Pandemic Planning Toolkit or require assistance in coordinating an antiviral program for your employees, please contact Roche:

Phone: Pandemic Planning Hotline: (800) 551-2231

E-mail: Nutley.TAMIFLU_Inquiry@Roche.com

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Step 4 Store TAMIFLU for your organization

It is important to consider where and how your organization will store the supply of TAMIFLU it receives. TAMIFLU capsules are supplied in blister packages of 10 (NDC 0004-0800-85). They are 75 mg grey/light yellow hard gelatin capsules. “Roche” is printed in blue ink on the grey body, and “75 mg” is printed in blue ink on the light yellow cap. The following checklist will help you to select a suitable storage site.

■ Understand criteria for TAMIFLU storage

An organization can store product at any entity that meets ALL of the following criteria:

- Has a Drug Enforcement Agency (DEA) number, which permits an individual to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research
- Has on file a controlled substances registration (CSR)
- Adheres to these TAMIFLU storage requirements:
 - TAMIFLU capsules must be stored at 25° Celsius (77° Fahrenheit); excursions permitted to 15°C to 30°C (59°F to 86°F)
- Adheres to storage guidelines of United States Pharmacopeia (USP), available at: www.usp.org/patientSafety/newsletters/qualityReview/qr401994-06-01c.html
- Has sufficient and appropriate storage based on order quantity and distribution plan

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■ Identify and contact entities and evaluate their capacity to store TAMIFLU for your organization

In most cases, an organization can store product at any of the following locations:

- Company warehouse or storage facility in compliance with the aforementioned criteria
- Pharmaceutical wholesaler
- Specialty distributor
- Pharmacy benefit manager
- Company or community clinic
- Physician's office

NOTES: Other options may exist. Not all companies will be able to store product.

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Step 5 Facilitate consultations for your employees

TAMIFLU is a prescription medication and according to federal law requires a prescription written by a licensed physician^a or other qualified healthcare professional (HCP)^b. Consequently, for each individual the organization intends to receive TAMIFLU, a physician or HCP MUST verify that the employee's health meets appropriate prescribing criteria (see *TAMIFLU Background, Package Insert*) by conducting a consultation, and then issuing a prescription. The following checklist will help you to select the best model for conducting consultations.

■ Assess your organization's needs and on-site resources

1. Does your organization have employee health or clinical services located on-site?
2. How many employees will require physician consultations?
3. Will your organization require consultations at a single location or multiple locations?

■ Identify entities able to conduct employee consultations and write prescriptions

- Employee health services/on-site clinic
- Local/community clinic or physician group
- Corporate healthcare providers (not all corporate healthcare providers offer a program)

^aIncludes dentists, podiatrists and veterinarians. In some states, licensed physicians may need to sign off on prescriptions. Dispensing licenses are governed by the State Board of Pharmacy for pharmacies and the State Board of Medical Examiners for physicians. Please consult your state pharmacy laws for local requirements.

^bIncludes midlevel practitioners (eg, registered nurses, physician assistants) meeting certain state requirements.

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■ Determine which type of entity is right for your organization

Consider the following:

- An employee health or clinical services group located on-site may be able to handle all employee consultations, contingent upon:
 - Number of employees receiving consultations
 - Desired program timeline
 - Number of qualified and dedicated staff available
- Large numbers of employees receiving physician consultations could challenge on-site clinical services as well as a local clinic or physician group, resulting in disruption of the normal corporate clinical services
- Organizations with multiple worksites may find it challenging to internally coordinate a program. Additionally, it may be challenging to find affiliated clinics or physician groups across multiple worksites
- Corporate healthcare providers are ideal for large organizations that lack on-site clinical services or have multiple worksites or a geographically distributed workforce (eg, a sales force) since they often have dedicated medical staff as well as networks of affiliated clinics and providers

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■ Discuss employee consultation issues with candidate entities to make your decision

Consider:

Program Duration

- How long will the program be offered?
- How many consults can be conducted in a given day?
- How will new employees or employees who missed a consult be served?

Program Logistics

- Can the entity handle organizations with multiple worksites or a geographically distributed workforce?
- How will consultations translate into prescriptions? Where will the prescriptions be stored?

After a prescription has been written, the information can be stored in a database for use when your company determines when to distribute the product. This information can also be used to verify who has completed required educational training prior to distributing TAMIFLU to employees.

- Does the entity have the ability to provide a turn-key solution (ie, a solution that encompasses consultations, storage and distribution)?

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Step 6 Educate employees about pandemic flu and TAMIFLU

Employee education is an important component of your antiviral stockpiling program. Specifically, your organization may consider an educational program on pandemic flu and TAMIFLU for employees before they receive product.*

Employee education options:

- Computer-based training
- Webinar/Webcast
- In-person training
- Home study of educational materials

*Training materials can be designed internally or by a third party, such as a business advisory firm or a corporate healthcare provider.

Topics to include in employee educational program

- What is seasonal influenza?
- What is pandemic influenza?
- What are the differences between seasonal influenza and pandemic influenza?
- What is TAMIFLU?
- How should TAMIFLU be used during a pandemic?
- When should TAMIFLU be used during a pandemic?

For an example of an educational training guide for your employee antiviral program, please refer to www.PandemicToolkit.com.

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Step 7 Distribute TAMIFLU to employees

The method and timing of TAMIFLU distribution to employees is specific to each organization's pandemic plan. Consider the merits/challenges of various options before making a final determination. Similar to the employee consultation process, the choices made in preceding steps may influence your distribution plan. Answering these questions will help guide your decisions regarding TAMIFLU distribution.

■ How will the organization use TAMIFLU?

The company should define the role of TAMIFLU during a pandemic. Here are the three most likely roles:

1. *Maintain* a cache of TAMIFLU for treatment of on-site employees when they appear to have flu symptoms, or for prevention when on-site employees may have been exposed to someone with flu symptoms
2. *Distribute* TAMIFLU in advance to employees to keep at home so they can use it as needed in the event of a pandemic
3. *Distribute* TAMIFLU in advance to employees to keep at home so they can use it as needed in the event of a pandemic, AND *maintain* a cache of TAMIFLU for on-site employees

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■ Should distribution to employees be centralized or direct?

Centralized distribution

- Product can be dispensed to employees from a central distribution point (eg, on-site clinic) during a pandemic or at any other predetermined trigger point
- If distribution is limited to on-site employees, this may be the optimal strategy

Issues to consider

- **Number of eligible employees:** Large numbers of employees could make dispensing TAMIFLU logistically impractical in a time of crisis
- **Number of sites:** Organizations with multiple sites will require clinics and staff at all sites during a pandemic
- **Storage of product:** If product is stored at an off-site location, it may complicate distribution logistics
- **Security:** Organizations may require increased security
- **Infection control:** Centralized distribution may increase the risk of transmitting infection
- **Access:** Gaining access to the corporate campus or office building may be challenging during a pandemic

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Direct distribution to employees

- TAMIFLU can be shipped directly to employees at their home to ensure that they have product available during a pandemic. The organization can coordinate the distribution of TAMIFLU at a predetermined pandemic event-phase with the assistance of a distribution partner
- May be the optimal distribution strategy for organizations with large numbers of employees, a distributed workforce or for organizations that do not have on-site clinical services or storage capacity available

Issues to consider

- Lost or damaged product: Employees who receive TAMIFLU in advance may be at a greater risk of misplacing or damaging the product
- Inappropriate usage: Employees who receive TAMIFLU in advance may be at a greater risk for misuse of TAMIFLU. However, with appropriate education, resources and ensuring that employees contact a healthcare professional prior to administration, the risk can be sufficiently mitigated

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■ Who will help your organization with distribution?

Identify a distribution partner

- Prescription benefit managers
- Pharmaceutical wholesalers
- Specialty distributors

■ When will you distribute TAMIFLU to employees?

When to distribute is specific to your company's pandemic plan. Consider the following possible options:

- Immediately upon receipt of the organization's TAMIFLU order
- When public health officials declare that a specific phase of the pandemic has been reached (please refer to www.who.org for the current pandemic phase⁴⁹)
- When certain event-triggers are met in accordance with your organization's pandemic plan
- When employees require antiviral therapy due to pandemic flu

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TAMIFLU[®] (oseltamivir phosphate) **Indications and Safety Information**

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.

In treatment studies in adult patients, the most frequently reported adverse events (incidence ≥ 1 percent) were nausea and vomiting. Other events reported numerically more frequently in patients taking TAMIFLU compared with placebo were bronchitis, insomnia and vertigo. In treatment studies in patients 1 to 12 years old, the most frequently reported adverse event (incidence ≥ 1 percent) was vomiting. Other events reported more frequently in patients taking TAMIFLU compared with placebo included abdominal pain, epistaxis, ear disorder and conjunctivitis.

In prophylaxis studies in adult patients, adverse events were similar to those seen in the treatment studies. Events reported more frequently in patients taking TAMIFLU compared with placebo (incidence ≥ 1 percent) were nausea, vomiting, diarrhea, abdominal pain, dizziness, headache and insomnia. In a household prophylaxis trial that included patients 1 to 12 years old, adverse events were consistent with those observed in pediatric treatment studies, with GI events being the most frequently observed.

Please see accompanying complete Prescribing Information.



TAMIFLU[®] (oseltamivir phosphate) **Indications and Safety Information** (cont'd)

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. Safety and efficacy of repeated treatment or prophylaxis courses have not been studied.

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

Vaccination is considered the first line of defense against influenza.

Please see accompanying complete Prescribing Information.