



TAMIFLU FACT SHEET

TAMIFLU BACKGROUND

- ? **Tamiflu is the only prescription antiviral medication indicated to treat type A and type B influenza in patients one year and older.**
 - ? **Tamiflu** (oseltamivir phosphate) was approved by the U.S. Food and Drug Administration in October 1999 for the **treatment of uncomplicated acute illness due to influenza infection in adults.**
 - ? **Tamiflu oral suspension** was approved in December 2000 for use in the **treatment of influenza A and B in children one year and older.** Tamiflu oral suspension can also be used in adult patients who cannot swallow a capsule.
- ? Vaccine is the first line of defense in preventing influenza, but antiviral medications can also be used for prophylaxis. **Tamiflu** was granted FDA approval in November 2000 for the **prevention of influenza in adults and adolescents 13 years and older.**
- ? The suggested dose for Tamiflu capsules is 75 mg, twice daily for five days of treatment. Treatment should begin within two days of onset of symptoms of influenza. For prevention, Tamiflu should be taken once daily for at least seven days. Safety and efficacy have been demonstrated for up to 6 weeks. The duration of protection lasts for as long as dosing is continued.
- ? Tamiflu targets one of the two major surface structures of the influenza virus, the neuraminidase protein. The neuraminidase site is virtually the same in the most common strains of influenza, types A and B. **Tamiflu attacks the influenza virus and is thought to work by stopping it from spreading inside the body.** Tamiflu treats flu at its source, by attacking the virus that causes the flu, rather than simply masking symptoms.
- ? Tamiflu ended the 2003-2004 flu season with close 98 percent of the market share within the class of antivirals called neuraminidase inhibitors and garnered more than 60 percent of the overall influenza antiviral market. Tamiflu is approved in over 40 countries including the United States, Japan, Canada, Switzerland, South Africa, Australia, New Zealand, Mexico, Brazil, Peru, Chile, Argentina as well as several other Latin American countries.

CLINICAL TRIALS

- ? In clinical trials, patients who took Tamiflu felt better sooner (30% faster) than patients who did not take Tamiflu. The results of several clinical studies show that **Tamiflu is up to 92 percent effective in preventing influenza in adolescents, adults and the elderly when taken once daily for seven days.**
- ? Tamiflu is generally well tolerated. In treatment studies in adult patients, the most frequently reported adverse events were mild to moderate transient nausea or vomiting.

PEDIATRIC CLINICAL STUDIES (Treatment Indication)

- ? Roche was granted FDA approval in December 2000 for the treatment of acute illness due to influenza in children 1 year and older who have been symptomatic for no more than two days. The suspension for pediatric patients can also be used for adults who cannot swallow a capsule.
- ? The results of pediatric clinical studies show that Tamiflu reduced the duration of certain symptoms of influenza by **1.5 days** in children aged 1-12 when given within two days of onset of symptoms.
- ? Tamiflu was well tolerated in pediatric studies.

For further information, please visit www.tamiflu.com.
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