

# Single-Dose Oral Antiviral Therapy Found To Accelerate Healing Time Of Cold Sore Outbreaks

(NAPSA)—You sense a tingling on your lip that, in a day or two, turns into a red blister. It's a cold sore and it's difficult to hide or get rid of easily.

With approximately 100 million episodes of recurrent cold sores occurring annually, all too many Americans are familiar with this common condition. Cold sores, medically known as herpes labialis, are an infection of the mouth area with the herpes simplex virus. In fact, it is estimated that cold sores affect 66 percent of American adults—with most being infected by the age of 20 years. Also known as fever blisters, cold sores typically appear as eruptions of small and usually painful blisters on the skin of the lips, mouth or gums or the skin around the mouth.

Although there is no cure for cold sores, new medical research found that a single dose of the prescription antiviral Famvir® (famciclovir tablets), given to patients with recurrent cold sores at the first sign of symptoms (within the first hour), resulted in significant improvements in healing time and resolution of pain and tenderness. This study is the first of its kind to show the benefit of a full course of antiviral therapy in a single dose when the virus is most active.

"These results are exciting news for the millions of people who suffer from cold sores each



**Sixty-six percent of American adults are affected with cold sores, mostly women.**

year. This research showed that Famvir was an effective treatment option that provides a full course of therapy in a single dose by taking the medication during the first few critical hours of an outbreak when the infection is most active," said Dr. Spotswood Spruance, Professor of Medicine, Division of Infectious Diseases at the University of Utah School of Medicine, and lead investigator in the study. "The implications of this study are important to physicians because the results may have the potential to significantly influence the overall management of cold sore outbreaks."

Dr. Spruance also noted that when the herpes virus is "triggered" in the body, it is most active during the first hours of a cold sore

outbreak, creating a narrow window of opportunity for treatment. According to this research, when patients were treated with the oral antiviral Famvir during this critical period of time, it shortened the duration of outbreaks and hastened the resolution of symptoms associated with cold sore outbreaks in many patients.

Based on these findings, Novartis Pharmaceuticals Corporation, the maker of Famvir, filed a supplemental new drug application (sNDA) with the U.S. Food and Drug Administration (FDA) for a single-dose Famvir treatment indication for immunocompetent patients with recurrent herpes labialis (cold sores) in the fall of 2005.

## Facts About Cold Sores

- It is estimated that cold sores affect 66 percent of American adults—with most being infected by the age of 20 years.
- Annually, approximately 100 million episodes of recurrent cold sores occur in the U.S.
- There is no cure for cold sores.
- Oral antiviral medications can shorten the course of an outbreak and improve the time to resolution of symptoms (pain and tenderness) associated with cold sores.

For more information about Famvir, see the full Prescribing Information on the Web site at <http://www.famvir.com>.

*Note to Editors: For more information about genital herpes, go to [www.genitalherpes.com](http://www.genitalherpes.com). Famvir (famciclovir) tablets are indicated for the treatment or suppression of recurrent genital herpes in immunocompetent patients; the treatment of recurrent mucocutaneous herpes simplex infections in HIV-infected patients; and the treatment of acute herpes zoster (shingles). In clinical trials, the most commonly reported adverse events vs. placebo were headache (zoster: 22.7% vs. 17.8%; episodic: 23.6% vs. 16.4%; suppression: 39.3% vs. 42.9%); nausea (zoster: 12.5% vs. 11.6%; episodic: 10.0% vs. 8.0%); and diarrhea (zoster: 7.7% vs. 4.8%; suppression: 9.0% vs. 9.5%).*

*The efficacy of Famvir has not been established for initial-episode genital herpes infection, ophthalmic zoster, disseminated zoster, or in immunocompromised patients with herpes zoster. The safety and efficacy of Famvir for suppressive therapy have not been established beyond one year.*

*There is no cure for genital herpes. There is no evidence that Famvir can stop the spread of herpes to others.*

*Famvir, Pregnancy Category B, is contraindicated in patients with known hypersensitivity to the product, its components, or Denavir® (penciclovir cream).*

*See the full Prescribing Information at [www.famvir.com](http://www.famvir.com) for more information about Famvir.*