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

You sense a tingling on your lip that, in each day or two, turns into a red blister. It is a cold sore and it is 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 referred to as herpes labialis, are an infection of the mouth area with the herpes simplex virus. In fact, it's estimated that cold sores impact 66 percent of American adults--with most becoming infected by the age of 20 years. Also referred to as fever blisters, cold sores typically appear as eruptions of small and generally 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 study discovered that a single dose of the prescription antiviral Famvir® (famciclovir tablets), given to patients with recurrent cold sores at the first sign of symptoms (inside the first hour), resulted in substantial improvements in healing time and resolution of pain and tenderness. This study will be 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 individuals who suffer from cold sores each year. This study showed that Famvir was an effective treatment option that offers a full course of therapy in a single dose by taking the medication throughout the very first couple of critical hours of an outbreak when the infection is most active," stated Dr. Sprounce, Professor of Medicine, Division of Infectious Diseases at the University of Utah School of Medicine, and lead investigator within the study. "The implications of this study are essential to physicians simply because the outcomes may have the possible to substantially influence the overall management of cold sore outbreaks."

Dr. Sprounce also noted that when the herpes virus is "triggered" in the body, it is most active throughout the first hours of a cold sore outbreak, creating a narrow window of opportunity for treatment. According to this research, when patients were treated using the oral antiviral Famvir during this crucial period of time, it shortened the duration of outbreaks and hastened the resolution of symptoms related to 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.

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

Note to Editors: For more information about genital herpes, go to 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, probably the most commonly reported adverse events vs. placebo had been 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 isn't any cure for genital herpes. There isn't any evidence that Famvir can quit the spread of herpes to other people.

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

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