



**Press Release, 21 December 2009**

## **First OTC pharmaceutical that can prevent herpes cold sores approved in Sweden**

**The Swedish Medical Products Agency has now approved Xerclear™ for treatment of cold sores. It is the first and only topical treatment that has been demonstrated to prevent the incidence of cold sores and shorten healing-times. Xerclear™ will be available from pharmacies in the first half-year 2010.**

One in four Swedes are regularly affected by cold sores (herpes labialis).<sup>1</sup> Current therapies shorten healing-times but have not been clinically demonstrated to be able to prevent the incidence of cold sores.

"Xerclear™ has two active ingredients with antiviral and anti-inflammatory effects. With early treatment onset, many people can completely avoid herpes cold sores. Xerclear™ is a completely new concept for treating labial herpes, which has also been demonstrated to have a far superior therapeutic effect for patients. If the occurrence of cold sores can be prevented, this is obviously a great relief for patients with repeated labial herpes," commented Johan Harmenberg, MD, Associate Professor of Virology and one of the originators of Xerclear™

Earlier this year, Xerclear™ (acyclovir 50 mg/g + hydrocortisone 10 mg/g) was approved in the US and Europe. The Swedish Medical Products Agency has now issued its final statement of opinion, implying that Xerclear™ will be released in Sweden, with 5g tubes available on prescription in the first quarter of 2010. The over-the-counter 2g tube will be available in the second quarter of 2010. The label reads:

"Treatment of early signs and symptoms of recurrent herpes labialis (cold sores) to reduce the progression of cold sore episodes to ulcerative lesions in immunocompetent adults and adolescents (12 years of age and older)".

None of the pharmaceuticals to treat herpes cold sores currently available on the market, over-the-counter or on prescription have the corresponding label, indicating that the incidence of a cold sore outbreak can be prevented with early treatment onset.

### **Four out of ten patients completely avoid cold sores**

Extensive clinical trials, which were able to demonstrate that the incidence of cold sores can be prevented with pharmaceutical treatment for the first time ever formed the basis of the approval of Xerclear™. Cold sore outbreaks were prevented in 42% of the patients that started treatment when early symptoms occurred. The trials also demonstrate that Xerclear™ reduces healing-times for patients that do develop cold sores by one and a half days compared to placebo. The trials demonstrated that the combination of acyclovir (antiviral) and hydrocortisone (anti-inflammatory) has a better therapeutic effect than acyclovir alone.<sup>2</sup>

Cold sores are caused by the herpes simplex virus and the body's inflammatory reaction to this virus. The combination of antiviral and anti-inflammatory effect means that Xerclear™ can prevent the incidence of cold sore lesions. Acyclovir specifically inhibits propagation of the herpes simplex virus—hydrocortisone reduces the inflammation. Xerclear™ is approved for the treatment of adults and young people aged 12 and above. The pharmaceutical will be available for OTC treatment in 2g tubes, and in 5g tubes on prescription. To attain the best effect, treatment with Xerclear™ should start as soon as possible after the first symptoms of a herpes outbreak.

### **About Medivir**

Xerclear™ has been developed by Medivir in Stockholm, Sweden. Medivir is active in the research and development of pharmaceuticals against a range of diseases, including hepatitis C, osteoporosis, HIV and shingles. The company has a range of partnerships with established pharmaceutical companies and smaller biotech enterprises on clinical and preclinical projects. Xerclear™ is the first pharmaceutical Medivir has developed in-house, which it is launching.

1.) [www.apoteket.se](http://www.apoteket.se)

2.) C. Hull. Episodic Treatment with Topical ACV/Hydrocortisone Prevents Cold Sores: A Randomized, Double-Blind, Patient-Initiated Clinical Trial. Poster Presentation 49th ICAAC meeting in San Francisco, USA (2009).

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**For more information on Medivir, please go to [www.medivir.com](http://www.medivir.com)**