



## **Cold-fX® for Colds and Flu: Effectiveness and Safety?**

What do Mark Messier, Margaret Atwood, and Don Cherry have in common? They all believe in taking Cold-fX® to prevent and treat the common cold and flu, and they are more than willing to talk about it.

In 2007, Health Canada issued Cold-fX® a product license, a natural product number, and authorization to make the claim that Cold-fX® helps reduce the frequency, severity and duration of cold symptoms by boosting the immune system.<sup>1</sup> Also, Cold-fX® is now available in the United States. Considering Cold-fX® costs approximately \$400 for a year's supply, is Cold-fX® safe and effective?

The dosage regimen recommended by the manufacturer of Cold-fX® for prevention is 200 mg twice daily for prevention. For immediate relief of symptoms, the recommended dose is as follows: Day 1 – 900 mg twice daily, Day 2 – 600 mg twice daily, Day 3 – 300 mg twice daily.<sup>2</sup> Cold-fX® is available in 200 mg and 300 mg (Extra Strength) capsules.<sup>2</sup> There have been seven clinical trials involving up to 641 subjects aged 18 to over 80.<sup>2</sup>

### **Does Cold-fX® interact with any other medications?**

Cold-fX® is a herbal product that contains American ginseng (*Panax quinquefolium*); therefore, patients could theoretically be at risk for drug interactions specifically with antidiabetic agents, MAOIs, and warfarin.<sup>3</sup> Cold-fX® does not appear to affect the major drug-metabolizing enzymes of the liver as demonstrated by laboratory studies.<sup>2</sup> Cold-fX® has not been shown to interact with any medications during clinical trials; however, no clinical trials have specifically looked for drug interactions or reported if subjects were on other drugs.<sup>2</sup> There are no known herbal or supplement interactions with Cold-fX®.<sup>2</sup>

### **Does Cold-fX® have any side effects?**

Cold-fX® has not been shown in clinical studies to cause side effects at the doses used in the acute regimen or the prevention chronic regimen.<sup>2</sup> The manufacturer states that no adverse effects were noted in laboratory trials when a dose of Cold-fX® 500-times greater than normal was given once or when doses of Cold-fX® 25-times greater than normal were given for 30 days.<sup>4</sup>

### **Is Cold-fX® safe for everyone to use? <sup>2</sup>**

Cold-fX® has not been studied in children under the age of 12, in pregnant or nursing women, +or in specific disease states. Cold-fX® has been shown to be safe in healthy populations. The manufacturer specifically recommends patients who have autoimmune diseases, hypertension, diabetes, or on warfarin should consult their physician before starting on Cold-fX® and monitor their condition during the Cold-fX® regimen. Cold-fX® should not be used in patients with a ginseng allergy.

**Should women who have cancer or have a family history of cancer not use Cold-fX®?**

The evidence is contradictory concerning whether American ginseng “feeds” hormonal cancers such as breast cancer.<sup>5</sup> There is no proof that Cold-fX® is harmful or safe for women with breast cancer.<sup>5</sup> At this point, it appears Cold-fX® is unlikely to cause a problem.<sup>5</sup> It is recommended to consult their physician prior to taking Cold-fX®.<sup>2</sup>

**Is Cold-fX® effective for treating colds?**

The product claims to produce immediate relief when 18 capsules are taken over a 3 day period at the first sign of an upcoming cold.<sup>2</sup> There is no evidence to support this claim and therefore Health Canada did not authorize this claim.<sup>1</sup>

**Is Cold-fX® effective for preventing colds?**

The Health Canada approved dosage for Cold-fX® is 200 milligrams (one capsule) two times a day to help reduce the frequency, severity and duration of cold symptoms by boosting the immune system.<sup>1</sup> The most recent Canadian clinical trial had subjects taking two Cold-fX® capsules daily for four months; Cold-fX® decreased the number of colds per person by 0.25 in those who had ≥2 colds in the previous year.<sup>6</sup> **Note: The most effective method for prevention of acute respiratory illnesses remains hand washing.**<sup>7</sup>

**Is Cold-fX® effective for preventing the flu?** <sup>4,7</sup>

The validity of a trial evaluating the effectiveness of Cold-fX® for preventing influenza in older adults was limited due to approximately 90% of subjects receiving the influenza vaccine, unusually low influenza attack rates, initiation of the study midway through the flu season, and relatively healthy subjects. **Note: Use of the influenza vaccine remains the mainstay to prevent influenza in the elderly.**

**Caution:** Cold-fX® is derived from American Ginseng which has been associated with drug interactions, adverse reactions, and safety concerns.<sup>3</sup> Cold-fX® states that because it contains saccharides and not ginsenosides, there is potentially less drug interactions and side effects.<sup>2</sup>

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References available on request and on-line at [www.druginfo.usask.ca](http://www.druginfo.usask.ca)

♪ *Happy Holidays To All* ♪

**Thank you to everyone who used our service over the past year. We hope the information provided was useful for you and your clients and look forward to your calls in the coming year.**

**Wishing you a joyous Christmas season  
and a New Year filled with peace and happiness,**

*Carmen Bell, Gary Berg, Karen Jensen, Yvonne Shevchuk*

**References:**

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- 2.) CV Technologies Inc. Cold-fX (homepage on the Internet). Cited 2007 April 3. Available from: <http://cae.cold-fx.com>.
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- 4.) Cold-fX (Standardized Oligo/polysaccharide Extract of Panax quinquefolium). Pharmacist's Letters/ Prescriber's Letter 2005 January; 21(1): 210118.
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- 6.) Jensen B, Regier L. Herbal information- Recent Developments. In: Jensen B, Regier L, editors. RxFiles-Drug Comparison Charts. 6 ed. Saskatoon: Saskatoon Health Region; 2007. p.67.
- 7.) North American ginseng extract (Cold-fX) for the common cold. Pharmacist's Letters/ Prescriber's Letter 2005; 21(12): 211212.