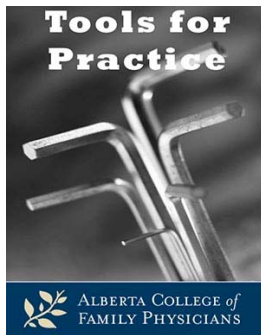


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December 13, 2011



## **COLD FX® evidence: consistently reported inconsistently**

**Clinical Question: Does CVT-002 (COLD FX®) reduce the chance of upper respiratory tract infections (URTI) or influenza?**

### **Evidence:**

Five industry-funded randomized controlled trials (RCT), in 4 publications:

- 783 patients  $\geq 65$  years old randomized to placebo or COLD FX® at 400 mg or 800 mg per day for 6 months during influenza season<sup>1</sup>
  - Modified intention to treat analysis found no statistical difference in either clinical or laboratory confirmed URTI.
  - In a per-protocol analysis (only subjects who completed the study), 2 of 8 outcomes were statistically significantly improved and 2 borderline.
- Combination of 2 non-statistically significant RCTs on nursing home seniors (89 and 109 patients each)<sup>2</sup> of placebo versus COLD FX® 400mg
  - Statistical difference in laboratory confirmed URTI and influenza (9% versus 1%  $p=0.009$ ) but not in clinical URTI or influenza.
- 323 patient (279 analyzed) RCT of 18-65 year olds (influenza vaccine naïve), demonstrated 0.25 fewer clinical URTI (0.93 reduced to 0.68) per person over 4 months in patients using COLD FX® 400mg/day.<sup>3</sup>
- 43 community patients  $\geq 65$  years old randomized to placebo versus COLD FX® 400mg<sup>4</sup>
  - Did not look at clinical URTI or laboratory URTI.
  - Statistically significant differences in some symptoms only seen in the last of 3 follow-up visits and no overall comparison.

### **Context:**

- Viral URTI occur in adults approximately 2-4 x per year.<sup>5</sup>
- COLD FX® trials suffer from many concerns: drop-outs  $>10\%$  before a single dose is taken,<sup>3</sup> modifying analysis to achieve statistical significance (using per-protocol

analysis,<sup>1</sup> combining trials,<sup>2</sup> or selecting certain time frames<sup>4</sup>), multiple analyses, laboratory not clinical outcomes,<sup>2</sup> and inconsistent results.

- Other reviews raise similar concerns with this research.<sup>6</sup>
- Hand washing<sup>7</sup> and getting an influenza vaccination<sup>8</sup> do appear to reduce the chance of influenza or an URTI (although this research too is potentially biased).

**Bottom-line: Much of the COLD FX® research is limited by trial design and reporting/analysis issues. The evidence is neither consistent nor convincing enough to recommend COLD FX® to prevent viral URTI in seniors or adults.**

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