

# Hua Fo tablets tainted with sildenafil-like compound

**Reason for posting:** Health Canada is ordering a recall of the Chinese herbal preparation Hua Fo because samples imported since 1999 have been found to contain a compound similar to the erectile-dysfunction drug sildenafil.<sup>1</sup> The product, which did not undergo laboratory testing as a part of its pre-marketing review, contains several recognized herbal compounds. It has been sold over the counter in Canada in both approved (DIN 02243366) and unapproved forms since 1999. Following a recent complaint that Hua Fo was being promoted inappropriately as a natural substance enhancing sexual function in both men and women, the product was tested and confirmed to contain a compound that is almost chemically identical to sildenafil. The compound is not naturally occurring. The advisory ordering a recall follows a notice issued in February 2002 telling Canadians not to use the product.<sup>2</sup> No adverse events involving this product have been reported in Canada.

**The drug:** Hua Fo is manufactured in China. The label for the 300-mg preparation claims that each tablet contains 18 mg of *Panax ginseng* root, 72 mg of *Ligustrum lucidum* fruit, 54 mg of *Cur-*

*culigo orchioides*, 84 mg of *Epimedium grandiflorum* ("licentious goat wort") and 72 mg of *Polgonum multiflorum* ("black-haired Mr. He"). The product's label says that it can restore mental alertness.

Sildenafil, marketed as Viagra, inhibits a specific cyclic GMP phosphodiesterase (PDE5) found in the smooth-muscle cells of the cavernosal arteries of the penis. When PDE5 is inhibited, nitrous oxide originating from both vascular and neuronal sources triggers increases in cyclic GMP in the cavernosal arteries, leading to vasodilation and, ultimately, an erection.<sup>3</sup> The drug has also been used in combination with the inhaled prostacyclin analog iloprost to treat severe pulmonary hypertension.<sup>4</sup>

Hypotension is a known adverse effect, likely because systemic and pulmonary arteries and venous smooth-muscle cells also contain PDE5. (For a complete listing of adverse events, see the product monograph.) The use of any nitrate medications, including sublingual and transdermal preparations of nitroglycerine and long-acting oral preparations such as isosorbide dinitrate, is a contraindication to sildenafil therapy because of the potential for prolonged and potentially fatal hy-

potension. Sildenafil is metabolized in the liver and excreted by both hepatobiliary and renal routes. It interacts with known cytochrome P450 inhibitors such as erythromycin, and therefore the 2 should not be administered concurrently.<sup>5</sup>

**What to do:** Physicians should routinely ask patients if they are consuming any herbal products. Many patients combine conventional and complementary therapies, often perceiving such a combination to be superior.<sup>5</sup> Unfortunately, as in the case of Hua Fo, the purity of many natural health products is unknown and the potential for serious adverse reactions exists. Patients being prescribed nitrates or being investigated for erectile dysfunction should be screened for the use of any erectile dysfunction treatments, including over-the-counter herbal preparations. Any patients with Hua Fo products should take them to a pharmacy for disposal.

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## References

1. *Health Canada warns public not to use Hua Fo (DIN 02243366)*. Ottawa: Health Canada; 2002 Apr 5. Available: [www.hc-sc.gc.ca/english/protection/warnings/2002/2002\\_26e.htm](http://www.hc-sc.gc.ca/english/protection/warnings/2002/2002_26e.htm) (accessed 2002 May 13).
2. *Health Canada warns public not to use Hua Fo*. Ottawa: Health Canada; 2002 Feb 15. Available: [www.hc-sc.gc.ca/english/protection/warnings/2002/2002\\_09e.htm](http://www.hc-sc.gc.ca/english/protection/warnings/2002/2002_09e.htm) (accessed 2002 May 13).
3. Michelakis E, Tymchak W, Archer S. Sildenafil: from the bench to the bedside [review]. *CMAJ* 2000;163(9):1171-5. Available: [www.cmaj.ca/cgi/content/full/163/9/1171](http://www.cmaj.ca/cgi/content/full/163/9/1171)
4. Ghofrani HA, Wiedermann R, Rose F, Olschewski H, Schermuly RT, Weissmann N, et al. Combination therapy with oral sildenafil and inhaled iloprost for severe pulmonary hypertension. *Ann Intern Med* 2002;136:515-22.
5. Eisenberg DM, Kessler RC, Van Rompay MI, Kaptchuk TJ, Wilkey SA, Appel S, et al. Perceptions about complementary therapies relative to conventional therapies among adults who use both: results from a national survey. *Ann Intern Med* 2001;135:344-51.

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