

FDA Warns Consumers to Discontinue Use of Botanical Products Containing Aristolochic Acid

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Based on new information, the US Food and Drug Administration (FDA) is advising consumers to immediately discontinue use of any botanical products containing aristolochic acid. These products may have been sold as "traditional medicines" or as ingredients in dietary supplements. There are many common names for aristolochic acid.*

Aristolochic acid is found primarily in the plant *Aristolochia*, but may also be present in other botanicals. Consumption of products containing aristolochic acid has been associated with permanent kidney damage, sometimes resulting in kidney failure that has required kidney dialysis or kidney transplantation. In addition, some patients have developed certain types of cancers, most often occurring in the urinary tract.

Previously, in May 2000, FDA alerted health care professionals and the dietary supplement industry of two patients in the United Kingdom who had experienced serious, permanent kidney damage following the use of botanical products containing aristolochic acid. These cases, along with the ones previously reported from Belgium and France, resulted in FDA imposing an import alert to detain botanical ingredients that are either labeled as "*Aristolochia*" or, for other reasons, are suspected to contain aristolochic acid. The ingredient will only be allowed to enter the U.S. when adequate testing shows that the suspect ingredients are free of aristolochic acid.

Recently, FDA has received reports of two patients in the U.S. who developed serious kidney disease associated with the use of botanical products that were shown by laboratory analysis to contain aristolochic acid. In addition, the agency analyzed a sample of 38 botanical products available in the U.S. that were labeled as containing *Aristolochia* or other herbs that might contain aristolochic acid and found that 18 of these products contained aristolochic acid. Based on these analytical results, FDA has requested that the involved U.S. manufacturers or distributors initiate recalls of these products.

Due to the potential serious public health risk, the agency is now advising consumers to stop using any products that may likely contain aristolochic acid. This includes products with the words "*Aristolochia*," "*Bragantia*" or "*Asarum*" listed as ingredients on the label, or any of the products FDA has found to contain aristolochic acid (see list of the 18 products analyzed by FDA - www.cfsan.fda.gov/~dms/ds-bot3.html). Consumers cannot be assured that products containing these ingredients are free of aristolochic acid unless they have been tested in a laboratory. To inquire about whether appropriate testing has been done, consumers may wish to contact the manufacturer or distributor of the product.

FDA advises consumers who have taken any of these products of concern to contact their health care provider immediately. Even if these products have not been used recently, consumers should still inform their health care provider about which product they took, so that an appropriate evaluation may be conducted.

* Common names for aristolochic include the following: *Aristolochia*, Guan mu tong, Guang mu tong, Oval leaf Dutchman's pipe, Ukulwe, Birthwort, Ma dou ling, Tian xian teng, Mil homens, Ma dou ling, Tian xian teng, Qing mu xiang Sei-mokkou (Japanese), Long birthwort, Guang fang ji, Fang ji, Mokuboi (Japanese), Kwangbanggi (Korean), Fang chi, Kou-boui (Japanese), Indian birthwort, Yellowmouth Dutchman's pipe, Dutchman's-pipe, Manchurian birthwort, Manchurian Dutchman's pipe, Guang mu tong, Kan-Mokutsu (Japanese), Mokuboi (Japanese), Kwangbanggi (Korean), Virginia snakeroot, *Serpentaria*, Virginia serpentary, Wild ginger, Indian ginger, Canada snakeroot, False coltsfoot, Colic root, Heart snakeroot,

Vermont snakeroot, Southern snakeroot, and Do-saishin

Current and past FDA activities and actions associated with aristolochic acid may be found at:
www.cfsan.fda.gov/~dms/ds-bot.html

Letter to Health Professionals
<http://www.cfsan.fda.gov/~dms/ds-bot13.html>

Listing of Botanical Ingredients of Concern
<http://www.cfsan.fda.gov/~dms/ds-bot2.html>

Botanical Products Determined by FDA to Contain Aristolochic Acids
<http://www.cfsan.fda.gov/~dms/ds-bot3.html>

US Food and Drug Administration MedWatch
<http://www.fda.gov/medwatch/safety/2001/safety01.htm#aristo>

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