

## Most top-selling, over-the-counter sexual treatments unproven, some could be harmful

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From horny goat weed to ginseng and maca, over-the-counter dietary supplements sold to improve male sexual health contain a wide variety of "natural" ingredients. Researchers from Wake Forest Baptist Medical Center reviewed the scientific evidence for the most common ingredients to determine if they are effective - and most importantly - safe. The results are published online ahead of print in the *Journal of Sexual Medicine*.

"While certain natural supplements we reviewed show promise for improving mild sexual dysfunction, they lack robust human evidence," said Ryan Terlecki, M.D., associate professor of urology and senior author. "In addition, because of concerns that some products are impure or weak, we do not routinely recommend these products to our patients."

For some products, there is no <u>scientific evidence</u> to support claims that can positively impact erectile function, libido and sexual performance. And perhaps most troubling, some products that are advertised as being "natural," contain traces of phosphodiesterase-5-inhibitors (PDE5Is), the same class of medication that includes prescription drugs such as Viagra, used to treat <u>erectile dysfunction</u>. One study revealed that 81 percent of tested samples of over-the-counter products purchased in the U.S. and Asia contained PDE5Is.

"PDE5Is cannot yet be legally sold over the counter in this country," said Terlecki. "Men who use these medications without a physician's supervision run the risk of taking them inappropriately. Patients with



advanced heart disease, for example, or who take nitrates, such as nitroglycerin, should not use PDE5Is as it may cause an unsafe drop in blood pressure. Likewise, men with severe liver impairment or end-stage kidney disease requiring dialysis should avoid these products."

In addition, Terlecki said, men with enlarged prostates who take medications such as Flomax (tamsulosin), terazosin or doxazosin need to know how to time the dosing of the two medications to avoid causing dizziness and potential falls, which may result in fractures.

An estimated 40 to 70 percent of men experience some form of sexual dysfunction during their lives. Due to concern regarding costs of prescription drugs, or embarrassment over discussing sexual concerns with their physicians, some men turn to over-the-counter products. According to a recent nationwide survey, 50 percent of respondents reported using dietary supplements for a variety of conditions.

"There is a dizzying array of formulations available and the health effects of nutraceuticals are often confusing to patients and medical practitioners alike," Terlecki said. "We reviewed the current evidence available for each of the ingredients in top-selling men's health products to provide urologists with a guide they could use to counsel their patients.

"Patients are paying more than \$5 per day to take products with no proven effectiveness," he said. Products included in the survey ranged in cost from 83 cents to \$5.77 per day.

In addition to the lack of scientific evidence for some products, Terlecki noted that purity is also a concern. Because dietary supplements are currently classified as foods, rather than drugs, it is the manufacturers themselves who are largely responsible for ensuring the safety, purity and efficacy of the products. Four major retailers have been targeted by



the New York attorney general for selling misleading supplements.

Below, the authors summarize some of the results of an extensive literature search for ingredients in top-selling <u>products</u>:

DHEA seems relatively safe as the data does not show a significant impact on hormone levels. The data is weak to suggest a benefit.

Fenugreek is seen in about a third of the top-selling men's <u>health</u> <u>supplements</u>. One study noted a benefit in terms of improving sexual arousal and orgasm, as well as muscle strength, energy and well-being. There were no adverse events reported in that study and other studies also show this to be a safe supplement.

Ginkgo Biloba has been marketed to treat numerous conditions. There is no convincing data to support its use in men with erectile dysfunction. It can cause headaches, seizures and significant bleeding, especially if patients are taking Coumadin.

Ginseng is the most common ingredient in top selling men's health supplements. It can cause headache, upset stomach, constipation, rash, insomnia and can lower blood sugar (caution in diabetics).

Horny Goat Weed is generally safe with rare reports of toxicity (fast heart rate and hypomania). There is no evidence in humans of benefit for sexual function.

L-arginine is the most common amino acid seen in men's health supplements, also in about a third of top sellers. It has the theoretical potential to improve erectile function in some patients and seems relatively safe. It has been associated, however with a drop in blood pressure, but without a significant change in heart rate.



Maca is the most common vegetable among top selling men's health supplements. In animal research, use of maca was associated with increased sexual behavior. There have been rare reports of toxicity, such as mild increase in liver enzymes and blood pressure.

Tribulus: No evidence of benefit in humans. Two reports of liver and kidney toxicity in young men taking high doses.

Yohimbine has shown promise for improving male sexual function in some studies.

This drug has been used for a long time. It can cause hypertension, headache, agitation, insomnia and sweating.

Zinc appears to be safe, but there is no evidence of benefit in normal individuals. Zinc deficiency is very rare in the U.S.

**More information:** Tao Cui et al. A Urologist's Guide to Ingredients Found in Top-Selling Nutraceuticals for Men's Sexual Health, *The Journal of Sexual Medicine* (2015). DOI: 10.1111/jsm.13013

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