

REVIEW ARTICLE

A Urologist's Guide to Ingredients Found in Top-Selling Nutraceuticals for Men's Sexual Health

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ABSTRACT

Introduction. Use of supplements is common among men seeking urologic evaluation for sexual health matters. With a dizzying array of formulations available and little regulation on the dosage, purity, or ingredients found in these products, the health effects of nutraceuticals are often confusing to patients and medical practitioners alike.

Aim. In this review, we set out to concisely summarize the data on ingredients found within the top-selling nutraceutical agents marketed for men's sexual health in order to provide a clinical guide for urologists.

Methods. We used sales data from the most popular retail provider of men's health supplements to identify the top-selling products marketed toward improvement of men's sexual health. We summarized the available information related to the ingredients, dosage, cost, and mechanism of action for these substances and performed an extensive literature search to identify and review the current evidence available for each of the most common ingredients found in these nutraceuticals.

Results. The top-selling nutraceuticals marketed for men's sexual health contain a blend of multiple supplements (up to 33 in one formulation identified), the most common being ginseng, tribulus, zinc, horny goat weed, B complex vitamins/trace minerals, fenugreek, L-arginine, maca, DHEA, ginkgo, and yohimbine. The currently available medical literature evaluating the efficacy of these substances is generally of low quality.

Conclusions. Despite the dearth of evidence supporting nutraceutical agents in the men's health arena, these substances are still commonly used by patients. As these products can affect the health and well-being of men presenting to a urology clinic, a familiarity with commonly used agents can help the urologist appropriately counsel their patients. **Cui T, Kovell RC, Brooks DC, and Terlecki RP. A urologist's guide to ingredients found in top-selling nutraceuticals for men's sexual health. J Sex Med 2015;12:2105–2117.**

Key Words. Nutraceutical; Dietary Supplement; Men's Sexual Health; Erectile Dysfunction, Decreased Libido

Introduction

Intimate health concerns among male patients are not uncommon, with an estimated 40–70% of men experiencing some form of sexual dysfunction [1]. Frequently, conversations concerning sexual health topics such as libido, erectile function, and sexual activity are hindered by feelings of embarrassment, concerns over drug cost or side effects, and the stigma of a sexual dysfunction diagnosis. Oftentimes, patients will turn to off-the-shelf

products because they can be purchased without physician prescriptions, recommendations, or oversight, thus allowing patients to avoid surveillance or documentation. The use of natural (possibly a misnomer in some instances) products and herbal remedies to improve men's sexual health is widely accepted in many cultures across the world and is increasing in popularity in the United States [2]. The annual sales of dietary supplements have doubled between 1999 and 2007, and a recent nationwide survey showed that over 50% of

respondents reported using these products [2]. It is estimated that over \$30 billion a year is spent out of pocket on complementary or alternative medicine [3].

The Dietary Supplement Health and Education Act of 1994 reclassified dietary supplements as foods, rather than drugs, and significantly reduced the Food and Drug Administration's (FDA) role in testing the safety and efficacy of these products [4]. As a result, manufacturers are largely responsible for ensuring the safety, purity, and efficacy of their own products. With reduced medical and FDA oversight, there are few resources for consumers to verify the ability of these products to deliver on their advertised effects or to investigate potential side effects. Physicians should be aware of the information regarding efficacy and toxicity for those substances commonly used by their patients. For example, products interfering with the hypothalamic–pituitary–testicular axis could affect hormone balance, fertility, sexual performance, and virility. Furthermore, the prevalence of sexual dysfunction secondary to comorbid conditions or to the use of prescription medication(s) renders it vital for providers to be aware of interactions relevant to commonly used supplements.

Of particular importance to urologists, many products advertised for male sexual enhancement are adulterated with undisclosed amounts of prescription pharmaceuticals. Specifically, phosphodiesterase type 5 inhibitors (PDE5I) have been found frequently in so-called “natural” products claiming to improve sexual function. One study analyzing over-the-counter products purchased in United States and Asia found either PDE5I or PDE5I analogs in 81% of the samples tested [5]. In fact, 20% of samples contained >110% the highest approved dosage for the given drug. A second study analyzing seized sexual enhancement products found a similar rate of adulteration, as 70% of samples contained sildenafil [6]. In addition to commonly prescribed agents, aminotadalafil, a non-FDA approved PDE5I has also been found as an adulterant [7]. The market penetration for these adulterated products is substantial, with one manufacturer producing over 1 million capsules per month of a product laced with a PDE5I [8].

Commonly Sold Products

General Nutrition Corporation (GNC) is the largest specialty retailer of dietary supplements in the United States with estimated annual revenue

of over \$2.6 billion. We identified the most popular agents marketed to improve men's sexual health by evaluating the 30 top-selling products according to GNC's website (Table 1). There was considerable variability in the amount of information provided for individual products regarding package contents. Most products listed multiple active ingredients with some listing over 20. While there were no obvious themes or trends in the content of individual products, we identified the substances most commonly named as active ingredients (Table 2).

A comprehensive search of Medline and Natural Medicines (formerly Natural Standard and Natural Medicines Comprehensive Database) was performed for the names of the top products and their most common active ingredients. Both name brands and generic names were utilized for query. Studies were evaluated for relevance to men's sexual health (erectile function, libido, and sexual performance) and reviewed for level of evidence. A summary of the currently available evidence pertaining to the most common ingredients of top-selling supplements was compiled and summarized. It should be noted, therefore, that this is not a review of only those nutraceuticals with high-level evidence. Given that the practicing urologist is likely to encounter patients taking the products most commonly sold, we used sales data to define inclusion criteria.

Evidence for Efficacy

Red Ginseng (Panax Ginseng or Korean Ginseng)

Ginseng is the most common ingredient among top-selling supplements for men's sexual health. It was present in 13 (43%) of the top 30 products, with reported doses ranging from 10 to 150 mg. The highest doses of ginseng are found in Now® Testo Jack 200 and MAGNA RX+—BOGO supplements.

Red ginseng exerts its mechanism by increasing production of nitric oxide (NO) through stimulatory effects on NO synthase, resulting in increased production of NO and blood flow into the corpora cavernosa. Its active ingredients, ginsenosides and ginseng saponins, have been shown to cause dose-dependent relaxation of smooth muscle within the corpora cavernosa in rabbit models, with increased intracavernosal pressure noted in a dose/duration related fashion [9]. These active ingredients, however, are distributed unevenly throughout the ginseng plant, and the concentrations in individual supplements can vary.

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