

Premarket Notification for Radix Ginseng in VI-28

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NEW DIETARY INGREDIENT NAME: RADIX GINSENG (Ginseng)

INTENDED USE: Radix Ginseng is intended for use as a dietary ingredient in the dietary supplement product VI-28. The dietary supplement product will contain 75 mg of Radix Ginseng per capsule, for a dietary intake of up to maximum 150 mg per day.

HISTORY OF USE/SAFETY EVIDENCE FOR NEW DIETARY INGREDIENT:

The history of use of Radix Ginseng can be established with a brief review of products currently offered in the United States that contain this ingredient. Examples of such products include FeminiCare™ dietary supplement, Viatexx™ dietary supplement, and Betterman™ dietary supplement. With regard to Betterman™ dietary supplement, attention would like to be directed to the short term study of American men administered the dietary supplement. It was determined that there were no side effects or adverse reactions following administration of the supplement¹.

Radix Ginseng is the dried root of Panax Ginseng (*Panax Ginseng C.A. Meyer, Araliaceae*). Pharmacologically, Radix Ginseng has an "adaptogenic" effect, which produces an increase in the body's defenses against outside stress factors and chemicals. According to Herbal Drugs and Phytopharmaceuticals, Radix Ginseng is not a therapeutic agent, but rather an agent which regulates the resistance of the organism to various outside influences². Further, Herbal Drugs, states that side effects are "...relatively rare and only with high doses and/or use over very long periods of time"³. Side effects include sleepnesses, nervousness, diarrhea, menopausal bleeding, and hypertony. The daily dosage as indicated by the literature is 1-2 grams⁴.

Evidence of the safety of the dietary ingredient is shown in the study performed on the dietary supplement VI-28. A summary of the study and a copy are attached herewith⁵.

¹ See page 3, "Research Studies on the scientific proof that BetterMAN improves erections and prostate...III. Short-term Study with American Men...".

² Wichtl, M. "Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice...", pp. 236-238.

³ Id. at pp. 237.

⁴ Id. at pp. 237, bottom, last column (boxed).

⁵ The letter from Dr. Laurence S.L. Shek and Anti-ageing Study show the results of administration of VI-28.

Based on the literature and in comparison to the intended use of Radix Ginseng in VI-28, it is believed that Radix Ginseng can reasonably be expected to be safe. Namely, literature shows Radix Ginseng administered at doses (1-2 grams daily) significantly higher than that of VI-28 (maximum 150 mg daily), with the result being no ill effects.

1,

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Research Studies

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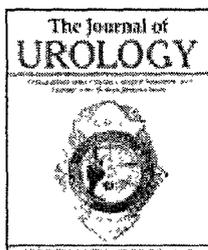
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I. University of California, San Francisco Scientific Study: BetterMAN Traditional Chinese Medicine (TCM) Formula Improves Erectile Function in Rats—Rules Out Placebo Effect



Erectile response was significantly better in the
(BetterMAN) treated group
—The Journal of Urology

The first scientific evidence of the beneficial effects of BetterMAN on penile tissue was published in the prestigious *Journal of Urology* (November 2000). The JU article reported on a study conducted by leading urologist, **Tom Lue, MD** at the University of California San Francisco, Department of Urology.

Dr. Lue, known throughout the world for his influential research in the field of impotency, wondered if any of the herbal dietary supplement formulas which claimed to improve ED actually worked. Dr. Lue was intrigued by the reported positive clinical outcomes of BetterMAN. He and his colleagues set out to see if it indeed worked, and if there was a scientific basis for its purported benefits. According to Dr. Lue, "The effectiveness of a product for ED can be ascertained more accurately in animals than in humans due to the absence of the placebo effect, which can run as high as 40% in human studies."

With this in mind, Dr. Lue conducted his study with hypercholesterolemic rats. Hypercholesterolemia is a factor known to contribute to ED in men. Rats naturally develop ED around the age of 24 months, which is equivalent to 70 human years. Previous research found that rats consistently develop ED after being fed a 1% cholesterol diet for 4 months.

Accordingly, rats in this study were fed a 1% cholesterol diet for 4

months. During the last two-month period, two groups of rats were fed the BetterMAN formula in their drinking water at two different dosages: 25 mg/kg per day and 50 mg/kg per day, while one group was fed water only. A separate control group of rats was fed a normal diet. At the end of the 4 months, 100% of the BetterMAN-treated rats regained their erectile function as evidenced by the normal peak-sustained intracavernous pressure, while all the rats in the non-treated groups remained impotent.

The groups receiving the BetterMAN formula showed no significant difference in cholesterol levels, systolic blood pressure, and neuronal and endothelial nitric oxide synthase (NOS) levels compared to the control groups. The most interesting results were the significant increases in membrane caveolae, caveolin-1, and basic fibroblastic growth factor (bFGF) protein levels in the penile tissue of the BetterMAN-treated groups.

Caveolin-1 is the major component of caveolae, small bulb-shaped invaginations at or near the cell surface, which act to sequester membrane-bound ligands away from extra cellular space and facilitate their delivery to the cell cytoplasm. UCSF researchers suggest that the substantial increases of caveolin-1 and caveolae may compensate or overcome the harmful effects of hypercholesterolemia on the smooth muscle and endothelial cells, and thus, reverse erectile dysfunction in the treated groups.

Basic fibroblastic growth factor (bFGF) protein level was also significantly higher in the BetterMAN-treated group as revealed by Western blot. This finding suggests that treatment with BetterMAN results in up-regulation of bFGF, which may reverse the suppressive effect of hypercholesterolemia on the smooth muscle and endothelium.

The significance of this study is that it rules out the placebo effect. The study also indicates that the activities of BetterMAN are very different from that of PDE-5 inhibitors, such as Viagra. Dr. Lue and his colleagues concluded that it is likely that more factors may be involved in the formula's ability to treat ED, and that larger scale studies are needed to determine the mechanisms of action of the formula and its effect on other organ systems.

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II. Ten-year Study of 5,000 Chinese Men Shows BetterMAN 75% Effective in Improving Sexual and Urinary Functions

Researchers at two of the largest medical hospitals in China compiled data on 5,000 men who had taken the BetterMAN formula between 1988 and 1997. Patients ranged in age from 35 to 65 and exhibited clinical symptoms of male sexual dysfunction: erectile dysfunction, premature ejaculation, low libido; as well as urinary problems. Physicians questioned patients regarding each symptom and recorded improvements (if any) based on each patient's self-assessment during office visits at the end of each cycle of treatment.

After taking the BetterMAN formula for 3x20-day cycles, 95% of patients reported various degrees of improvement in sexual performance and urinary control. Seventy-five percent reported a high degree of satisfaction. In most case reports, patients only noticed small improvements after the first cycle with major symptoms subsiding after

3,

completing 3x20-day cycles of the formula.

Fifty patients who used the formula continuously for 3 years reported experiencing an improvement in overall wellbeing, greater energy levels, and an ability to maintain their desired level of sexual performance and urinary control.

The compiled data showed BetterMAN to be a well-balanced formula providing the following benefits:

- Promotes both yin and yang functions of the kidney
- Enhances ability to attain and maintain an erection
- Improves sexual drive and libido
- Counters premature ejaculation
- Decreases nighttime urinary frequency, and urinary urgency and hesitancy
- Supports prostate health
- No side effects; safe to use

This data provides evidence that the BetterMAN formula is effective for Chinese men. However, an herbal formula proven effective with one ethnic group may not be equally effective for another due to a wide variety of factors, e.g., diet and metabolic differences. Prior to its introduction into the US market a study was designed to determine if BetterMAN would have a similar success rate with American men.

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III. Short-term Study with American Men: BetterMAN Found to be 70% Effective for Improving Sexual Functions and/or Urinary Control

Results from a 1997-98 independent study of American men indicate that even taken short-term, BetterMAN is 70% effective at enhancing sexual functions and promoting urinary control. In the study, 45 men between the ages of 41 and 71 were recruited to take BetterMAN at the suggested 3x20-day cycle (2 capsules daily after meals with a 3 day break between each bottle). The study was modeled after the A Brief Male Sexual Function Inventory developed at Harvard University to quantitatively measure the effects of BetterMAN pre-post three cycles of use.

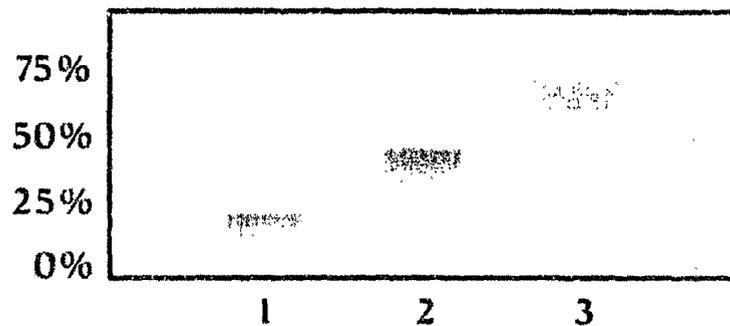
The following results were tabulated by a third party:

- 70%: Improved either sexual or urinary functions
- 60%: Improved sexual functions
- 68%: Improved urinary functions

Percentage of participants noticing improvements versus length of treatment:

25% after 1st cycle (bottle)
55% after 2nd cycle
70% after 3rd cycle

4.



There were no side effects or adverse reactions, and after the study, 90% of participants elected to continue taking BetterMAN.

(From "RESULTS FROM THE BetterMAN PRODUCT SURVEY", March 1998 by Pathfinder Research Group, Acton, Massachusetts. BetterMAN, formerly NuMAN)

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IV. 2001 Survey of American Users Confirms Claimed BetterMAN Sexual and Urinary Health Benefits

Two hundred and thirty BetterMAN users participated in a recent survey conducted between April 24 and May 8 2001. Participants were asked to complete an on-line questionnaire to assess whether BetterMAN had helped their sexual and/or urinary issues. A third party tabulated the results.

Of the 230 respondents, one-third had taken less than the recommended 3 bottles of BetterMAN, one-third had taken 3 bottles, and one-third had taken more than 3 bottles. Seventy percent were between 45 and 64 years old, 67% were married, and 96% described their current health status as either excellent (49%) or good (47%).

Even though 76 (33%) of the respondents had not finished taking the recommended 3-bottle cycle, the effectiveness rate of the BetterMAN formula with these respondents supports previous clinical results. Of those taking BetterMAN for the purpose of improving or enhancing a specific sexual and/or urinary health function, the following percentage noted an improvement:

- Decrease nighttime bathroom trips (91%)
- Improve urinary control (91%)
- Improve spontaneity of erections (84%)
- Improve sexual desire (78%)
- Improve erections (76%)
- Improve prostate health (76%)
- Delay ejaculation (64%)

More than half of the respondents (53%) claimed to have used Viagra, and 29% of those continued to use Viagra concurrently with BetterMAN in order to "Get the best of both products." Of those who had stopped using Viagra, the main reasons for no longer using it were:

5.

- Immediate side effects (40%)
- Prefer a natural alternative (37%)
- Not as effective as expected (38%)

Of those men who had never used Viagra, 54% cited a preference for a natural approach. Overall, men in the survey expressed a desire for a product offering a broad spectrum of benefits for their sexual health, rather than focusing on erection only.

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6.

[▲ Back to top](#)**Does BetterMAN have an effect on nitric oxide synthase (NOS) levels?**

No, BetterMAN does not have an effect at the enzyme expression level. Based on the findings of the UCSF study (see [Research Studies](#)), the mechanism of action of the BetterMAN formula appears to be very different from the PDE-5 inhibitors, such as Viagra, which impact NOS levels. BetterMAN provides spontaneous erections rather than a pill induced temporary response. In addition, BetterMAN also increases libido and supports prostate health.

Why should I try BetterMAN over other supplements?

- BetterMAN formula works —this proprietary herbal formula (not just 1 or 2 herbal components in a formula) is scientifically and clinically proven. BetterMAN is the only natural male sexual formula on today's US market which has published scientific evidence to support the formula's effect is not placebo.
- One formula provides broad spectrum of benefits for erectile functions and prostate health.
- No side effects with a long safety history spanning 50 years.
- No known contraindications with commonly prescribed medications.
- Not a stimulant; contains no hormones. BetterMAN functions steadily and continuously.
- No bio-resistance after years of regular usage—Many men have used BetterMAN regularly since 1998, and continue to experience incremental improvements in sexual and urinary health. Some "quick-fix" formulas on the market may work for you initially, but they tend to stop being effective after 3-6 months because they tend to further deplete your biosystem rather than gradually replenish your system as BetterMAN does.
- Guaranteed high quality without heavy metal contaminants; manufactured in the USA under current Good Manufacturing Practices (cGMPs) standards.
- Recommended by many physicians, urologists and pharmacists.

[▲ Back to top](#)**What are the ingredients in BetterMAN?**

BetterMAN is a proprietary blend of 18 pure, natural traditional Chinese herbs provided in capsule form. All herbs are screened for heavy metal contaminants, and we guarantee high quality. The product is manufactured in the USA under current Good Manufacturing Practices (cGMPs).

The botanical name of each of the 18 herbs in the proprietary BetterMAN

7.

formula is followed by the more common name and its key function in Traditional Chinese medicine (TCM) terms.

- *Radix ginseng* (Ginseng root): improves whole body vital energy (Qi) and sexual functions.
- *Rhizoma dioscoreae* (Yam rhizomes): improves the yang function of kidney.
- *Radix paeoniae alba* (White peony root): improves immune functions; acts as a vasodilator.
- *Herba epimedii* (Aerial parts of Epimedium): improves muscle and sexual functions.
- *Cornu cervi pantotrichum* (Deer antler): improves overall metabolism and sexual functions.
- *Radix astragali* (Astragalus root): improves immune system, whole body stamina and sexual functions via the central nervous system.
- *Poria cocos* (Poria fungus): provides tranquilizing effects, strengthens yang functions.
- *Radix morindae officinalis* (Morinda root): strengthens muscle and bone functions, enhances endocrine system functions.
- *Fructus corni* (Cornus fruit): improves yang function of kidney.
- *Cortex eucommiac* (Wood cotton bark): strengthens muscle and bone functions; low dose dilates peripheral blood vessels; high dose causes vasoconstriction.
- *Radix angelicae sinensis* (Dong quai root): improves blood circulation.
- *Fructus lycii* (Wolfberry fruit): improves immune system function and the yin function of kidney.
- *Radix rehmanniae* (Rehmannia root): improves immune system function and the yin function of kidney.
- *Rhizoma chuanxiong* (Szechuan Lovage root): improves blood circulation and dilates peripheral blood vessels.
- *Fructus schisandrae* (Schisandra fruit): improves yang function of kidney.
- *Acanthopanax senticosus* (Siberian ginseng): tranquilizing effect, improves sexual functions.
- *Cynomorium songaricum rupr* (fleshy stem of Cynomorium): improves immune system and endocrine system.
- *Cortex cinnamomi* (Cinnamon bark): improves yang function of kidney.

Is BetterMAN safe?

BetterMAN formula has been safely used in China for more than 10 years and in the US since 1998, no negative side effects have been reported; no contraindications with medications have been reported.

If you have a medical condition, take prescription medications, plan to have surgery, or are prone to allergic reactions, consult your urologist, physician, or health professional before taking any dietary supplement.

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How do I take BetterMAN?



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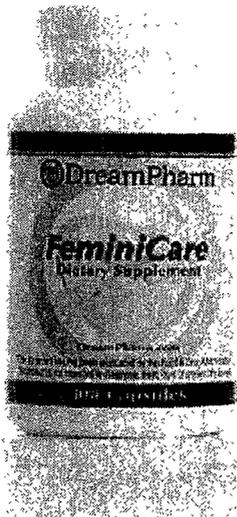
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Dose: 2 capsules 3 times a day after a meal.

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This formula helps to improve from common bodily weakness, facial paleness, anemia associated with weak pulse and insomnia, and debilitation of energy metabolism. **An excellent traditional chines herbal formula for women's health.**

Ingredients: Astragalus Radix,* Ginseng Radix, Atractylodes Rhizoma Sclerotium Poriae Cocos, Ziziphi Semen, Longanae Arillus, Angelica Sinensis Radix, Polygala Radix, Glycyrrhiza Radix, Saussurea Radix, Zingiberis Radix, Zizyphi Fructus (No yeast, no corn, no soy, no salt, sugar, no chemical, no preservative, no artificial color.)

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The products or nutrients discussed here are not intended to diagnose, treat, cure, or prevent any disease.

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Viatexx Ingredients

1. Ginseng Radix [Ginseng] (529):

Tonifying effect - acts on pituitary and stimulates the adrenal glands, thus increases the body's resistance to harmful stimulation or stress, and allows for extreme temperature changes, stimulates the nervous system - increases nervous impulses, analytical thinking & overall mental performance, and decreases fatigue and tension; Cardiotoxic effect - increases the heart contracting and slight blood pressure, stimulates sexual function; Hypoglycemic effect - lowers blood sugar, antidiuretic effect - causes retention of sodium, thus decreasing excretion of urine effect on digestion - increases protein synthesis, appetite, and lowers blood cholesterol, antihistamine actions.

2. Astragalus Radix [Astragalus] (521):

Traditional use - diuretic effect (induce fluid passage), is effective against degeneration of the kidney, shown to delay proteuria and high-blood cholesterol disease, cardiotoxic effect increases contraction of normal heart, vasodilation effect dilates blood vessels, improves blood circulation of the skin, enhances nutrition and immune system, antibacterial effect, hypotensive effect, lowers blood pressure due to its vasodilation action.

3. Angelicae Sinensis Radix [Tang-Kuei] (540):

Traditional use - headache due to deficiency of blood, regulates menses, chest and abdominal pain, constipation, functional bleeding. Has an uterus-regulating effect, effect on metabolism, relaxing effect, diuretic effect, antibacterial effect.

4. Bupleuri Radix [Bupluerum] (68):

Antipyretic effect - reduces fever from pseudomonas bacteria; Anti-hepatosis effect; Calming and analgesic effect; Anti-bacteria effect - Antiviral effect, antiphlogistic effect - anti-inflammatory.

5. Cimicifugae Rhizoma [Cimicifuga] (73):

Headache, chills and fever, sore throat, measles, diarrhea. Has an antipyretic effect, analgesic effect, antiphlogistic (inflammation) effect, anti-convulsive effect, anti-ulcer effect.

6. Citri Reticulatae Pericarpium [Citrus] (413):

Traditional use - Has a stomachic and expectorant effect. Traditional use for pain, coughing, vomiting, flushing up.

7. Zizyphi Fructus [Jujube] (538):

Traditional use - supplements and tonifies spleen and stomach, moistens heart and lungs, smoothes herbal action, harmonizes all drugs. Has an anti-allergic effect, anti-ulcer effect.

8. Zingiberis Officinalis Rhizoma [Fresh Ginger] (64):

Traditional use - cold and flu herb, nausea, vomiting, swelling, pain in chest and abdomen. Has an anti-emetic effect (inhibits vomiting), stomachic effect (stimulates gastroenteric activities), sudorific effect (stimulation of capillary blood circulation), antibacterial effect, lowering of blood pressure.

9. Glycyrrhizae Uralensis Radix [Licorice] (532):

One of the oldest and most popular herbs. Traditional use - harmonizes the stomach and spleen, diarrhea due to spleen deficiency, thirst due to stomach deficiency. Has a detoxifying effect, antispasmodic effect, gastric secretion-inhibiting action, anti-inflammatory effect, anti-ulcer effect, also antitussive, expectorant, anti-allergic, immune system effect.

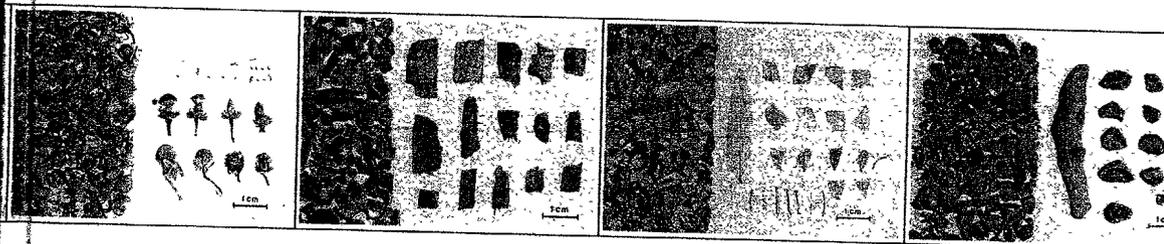
*Page references from Hsu Hong-Yen, *Oriental Materia Medica*, Oriental Healing Arts Institute 1986*

Norman Grainger Bisset (Ed.)

Max
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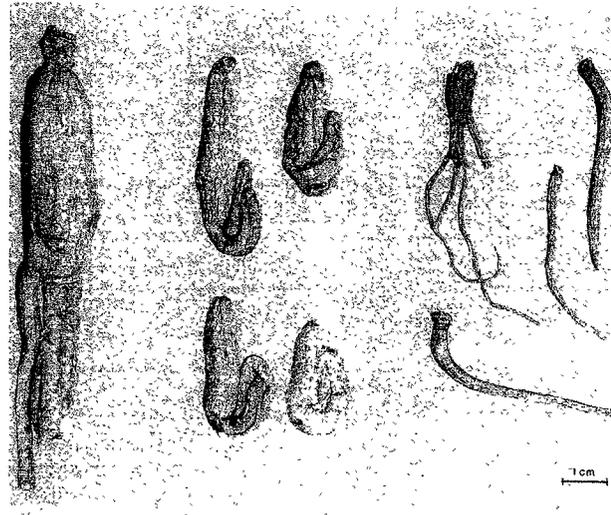
Ginseng radix (DAB 10), Ginseng (BHP 1/1990), Ginseng root

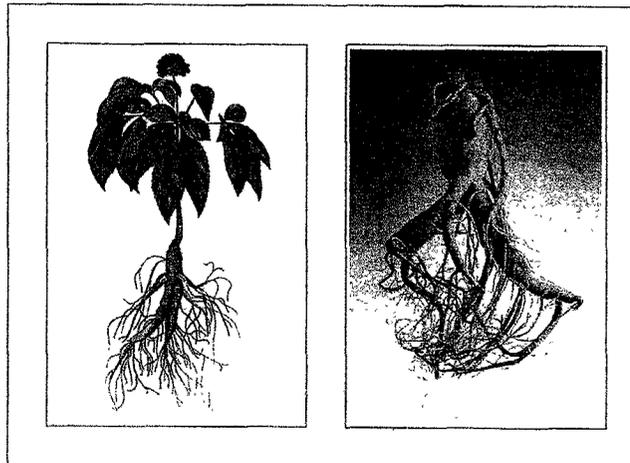
Fig. 1: Ginseng

There are several commercial varieties, including Korean ginseng, which is the most highly valued, followed by Chinese, Japanese, and American ginseng (this last variety comes mostly from *Panax quinquefolius*). Among the varieties of Korean ginseng, there are the white variety (official in the DAB 10, OAB, and Ph. Helv. VII), the roots of which after harvesting and washing are immediately dried, and the red variety, which is official in Japan and which are cartilaginous, translucent, and reddish as a result of the roots being first scalded for 1 1/2-4 hours and then dried. The illustration shows white ginseng - the commercial forms "curved" (centre) and "slender tails" (right; not official!).

Description: The cylindrical roots are transversely rugose in the upper part, from the middle sometimes repeatedly divided, and they taper towards the bottom. Often, the roots still bear the remains of the stem like a crown. The light yellow to light brown bark contains scattered small orange-red resin glands. Internally, the root is white to yellowish, cartilaginous, and brittle.

Odour: Faint and pleasant.

Taste: At first bitter, then sweet and mucilaginous.

Fig. 2: *Panax ginseng* C.A. MEYER

An up to 80 cm tall herb with palmate, verticillate leaves. Flowers small and grouped 15-20 in umbels.

Fig. 3: *Panax ginseng* C.A. MEYER, tap root and lateral roots

DAB 10: Ginsengwurzel
 ÖAB: Radix Ginseng
 Ph. Heb. VII: Ginseng radix

Plant source: *Panax ginseng* C.A. MEYER (syn. *Panax schinseng* NEES), ginseng (Araliaceae).

Synonyms: Panax, Korean ginseng (Engl.), Ginsengwurzel, Kraftwurzel (Ger.), Racine de ginseng (Fr.).

Origin: Native to the montane forests of eastern Asia. Cultivated in China, Japan, former USSR, and Korea. The drug is imported principally from Korea, China, and Japan; the root of *Panax quinquefolius* L. is imported from the United States (but it is not official).

Constituents: 2-3% Ginsenosides (triterpene saponins), of which ginsenosides Rg₁, Rc, Rd, Rb₁, Rb₂, and Rb₀ are quantitatively the most important (Russian investigators use the designations panaxosides A-F); ca. 0.05% essential oil (limonene, terpineol, citral, polyacetylenes); ubiquitous substances such as sugars, starch, etc.

More recently, a series of poly-acetylenes, the ginsenosynes A-K, some of which are acetylated, has been isolated [14].

Indications: Ginseng derives from East Asian medicine, where the drug has been used for thousands of years as a tonic (and presumably also as an aphrodisiac); it should therefore not be judged by the criteria of modern rational therapeutics. This drug is not a therapeutic agent for the treatment of particular illnesses, but rather a prophylactic which heightens in an unspecific way (details of which have only now been investigated scientifically) the resistance of

the organism to various environmental influences and stimuli and/or reduces the disposition or susceptibility to illness [1]. Nowadays, the "active principles" are considered to be the ginsenosides, some of which have been examined pharmacologically in detail, so that a very extensive literature is now available; but other ginseng constituents also have pharmacological activity. Interestingly, some of the ginsenosides have opposing activities, e.g. ginsenoside Rg₁ raises the blood pressure and is a central stimulant, while ginsenoside Rb₁ lowers the blood pressure and is a central depressant. The standardization of ginseng preparations is therefore of particular significance. Ginseng is an adaptogen, i.e. it is a substance that is able to improve the ability of an organism to adapt to differing external or internal disturbances [2].

The immunostimulant action of ginseng extracts has been repeatedly confirmed in animal experiments [3-5]. Various groups of workers have described in detail the enhancement of RNA and protein biosynthesis after administration of ginseng extracts [6, 7].

Also worth noting is the effect on carbohydrate and lipid metabolism; there are results from both animal experiments and clinical studies [8, 9].

Clinical work has demonstrated that ginseng affects human performance and ability to react in a positive way, though it has to be realized that the effect does not take place immediately (in Chinese medicine, ginseng has been, and is, taken over rather long periods of time).

Side effects: Relatively rare and only with high doses and/or use over very long peri-

ods of time. They include sleeplessness, nervousness, diarrhoea (particularly in the morning), menopausal bleeding, and hypertony [12]. See also [16].

Making the tea: Boiling water is poured over 3 g of the finely chopped drug, covered and allowed to draw for 5-10 min, and then passed through a tea strainer. The infusion is taken one to three times a day for a period of three to four weeks. Many manufacturers recommend taking the cut drug as such and chewing it.

1 Teaspoon = ca. 3.5 g.

Herbal preparations: The drug is offered in the form of an instant tea (and in 3 g tea bags).

Phytomedicines: The powdered drug (in some cases with a standardized ginsenoside content) or extracts as prepared geriatric remedies, e.g. Geriatric Pharmaton® (capsules), etc., and roborants and tonics, e.g. Ginsana® Ginseng, Kumsan Ginseng Much, etc.

Among the products available on the UK market are [15]: Blackmore's Ginseng Tablets, Vitalia Gerimax Tablets, Booker Healthcrafts Korean Ginseng Tablets, Herbal Laboratories Herbal Korean Ginseng Tablets, Larkhall Naturtabs Red Panax Ginseng, Unichem Pharmaton Capsules,

Extract from the German Commission
E monograph
 (BAnz no. 11, dated 17. 01. 1991)

Uses

As a tonic to combat feelings of lassitude and debility, lack of energy and ability to concentrate, and during convalescence

Contraindications

None known.

Side effects

None known

Interactions with other remedies

None known.

Dosage

Unless otherwise prescribed daily dose, 1-2 g drug; preparations correspondingly.

Mode of administration

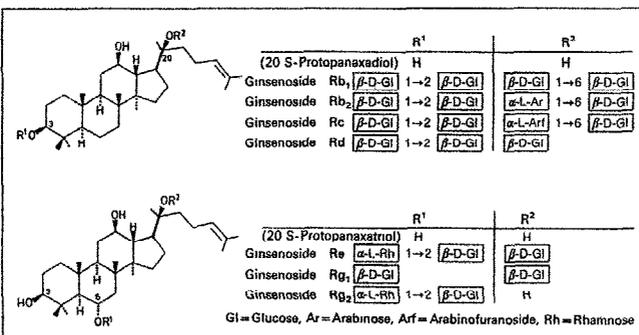
Comminuted drug for infusions, powdered drug and galemlcal formulations for internal use.

Duration of use

As a rule, up to 3 months

Effects

In various stress models, e.g. the immobilization test and the cold test, the resistance of rodents is increased



Power Ginseng GX 2500 Extract Capsules, English Grains Red Kooga Capsules and Tablets, Boots Second Nature Korean Ginseng Tablets, etc.

Authentication: Macroscopically, authentication is not possible with complete certainty, since the appearance of the commercial products varies considerably. Microscopical features include the occurrence of large secretory canals (only in the bark) containing a brownish yellow resin, whose size diminishes towards the inside; near the cambium, they form an almost continuous ring. Two- to four-seriate, to some extent tortuous medullary rays traverse the rather spongy parenchyma, the cells of which contain calcium-oxalate clusters and single crystals. There is abundant starch consisting of simple and aggregate grains. See also the BHP 1/1990. Microscopic examination does not allow the differentiation of *Panax ginseng* from *P. quinquefolius* [13]. However, the following TLC procedure, which is similar to that to that given in the DAB 10, can be used for this purpose:

Test solution: 1 g powdered drug refluxed with 10 ml 70% aqueous methanol for 15 min., cooled, and filtered.

Reference solution: 5 mg aescin, 5 mg amygdalin, and 25 mg arbutin, dissolved in 10 ml methanol.

Loadings: 5 µl test solution and 3 µl, as band, on silica-gel.

Solvent system: upper phase of: ethyl acetate + butanol + water (25+100+50), 6 cm run.

Detection: after drying in a current of hot air, sprayed with anisaldehyde reagent and heated at 105–110 °C for 2–3 min.

Evaluation: in daylight. **Reference solution:** aescin as a blue to blue-violet zone at Rf ca. 0.3, amygdalin as a greyish green zone at Rf ca. 0.5, and arbutin as a brown zone at Rf ca. 0.8. **Test solution:** greyish blue to greyish violet zones of the ginsenosides Rg₁ (Rf ca. 0.7) and Re (Rf ca. 0.55), between the arbutin and amygdalin reference zones, and Rb₁, at the same Rf as the reference aescin zone but not sharply separated from other ginsenosides (Fig. 4).

The following optimized HPTLC procedure enables various ginsengs, including red (steamed) and white (dried naturally), American, and sanchi (notoginseng), to be distinguished [17]:

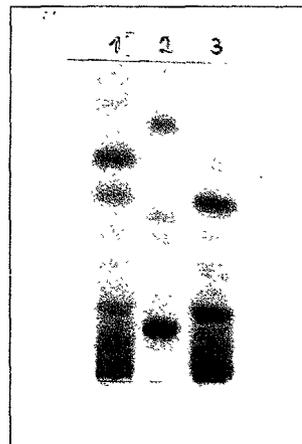


Fig. 4: TLC on 4 × 8 cm silica-gel foil

1: Official ginseng root
2: Reference substances
3: American ginseng (*Panax quinquefolius*)

For details, see the text

Test solution: 1 g powdered drug refluxed with 40 ml chloroform and the solution discarded; then refluxed for 1 h with 50 ml methanol and solution passed through a basic alumina column (15 g; 1 cm Ø), followed by elution with 50% methanol; hydrophilic components removed from the eluate with butan-1-ol and the solution taken to dryness in a vacuum desiccator over phosphorus(V) oxide; residue (ca. 8 mg) dissolved in 0.1 ml methanol (= crude ginsenosides); American ginseng and sanchi, 4 mg residue dissolved in 0.1 ml methanol.

Solvent system: lower phase of chloroform (no ethanol present) + ethyl acetate + methanol + water (15 + 40 + 22 + 10) after standing overnight at 8–10 °C, 7 cm run on silica gel 60F₂₅₄ at 26–28 °C for best results.

Detection: dipped in 5% ethanolic sulphuric acid for 2 sec., followed by heating at 105 °C for 1 min.; then dipped for 2 sec. in liquid paraffin + hexane (1 + 1) to stabilize the fluorescence for more than 24 h.

Evaluation: in UV 366 nm light. 19 zones divided into 4 groups: A (ginsenosides Ra, Rb₁, Rb₂, Rb₃), B (Rc, Re, Rd), C (Rg₁, Rf, F1, F2, Rg₂), and D (6 minor ginsenosides).

Macro-fingerprints (based on densitometric measurements): ginseng (group A > B ≥ C > D) pattern more complex than that of American ginseng (group A ≥ B > C > > D) and much more complex than that of notoginseng (sanchi); in red ginseng more minor ginsenosides (group D) than in white ginseng.

The clean-up stage causes some loss of ginsenosides, but the resulting extract gives better chromatograms.

Quantitative standards: DAB 10: Ginsenosides, not less than 1.5% calculated as ginsenoside Rg₁. Foreign matter, not more than 2%. Loss on drying, not more than 12%. Ash, not more than 8.0%. HCl-insoluble ash, not more than 1.0%.

ÖAB: 69–71% ethanol extractive, not less than 14%. Ash, not more than 4%. Ph. Helv. VII: Total ginsenosides, not less than 2.0% calculated as ginsenoside Rg₁ (M, 800.0). Sulphated ash, not more than 12.0%.

BHP 1/1990: 70% Ethanol extractive, not less than 20%. Foreign matter, not more than 2%. Loss on drying, not more than 10%. Total ash, not more than 8%. HCl-insoluble ash, not more than 2%.

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