

THE ALL-NATURAL, 100% PURE MENOPAUSE

just as we are puzzling through whether or not to undergo hormone-replacement therapy (HRT), the menopause-treatment menu gets more complicated. Now women who prefer a “natural” approach to the change of life can choose from a dizzying array of alternative remedies claiming to allay everything from night sweats and vaginal dryness to bone loss and wrinkles.

At a popular health-food store in Miami, for example, the hormone-replacement section is filled with shelf after shelf of these products—enough to give the uninitiated hot flashes. The choices range from female-directed formulations of the Chinese herb dong quai to rustic-looking containers of dried soybeans. Nearby are tiny pots of Vital Vulva wild-yam salve and a dozen other restorative skin creams; packages of tablets cryptically labeled Remifemin and Promensil; and vitamin look-alikes sporting names like Hot Flashex and Female Harmony.

Some remedies list amounts of ingredients; others don't. Many make health claims so vague as to leave the consumer guessing what the product actually does. Yet the mystery surrounding these beguiling potions has in no way lessened the demand for them. So-called “nutriceuticals” for menopause have mushroomed into a \$600 million market. Indeed, they now account for one of the largest segments of the nation's whopping \$4 billion alternative-remedy industry.

“A lot of women are scared of hormone-replacement therapy and see natural remedies as a kinder, less-aggressive intervention,” says Patricia Negron, an equity analyst who tracks

Herbs. Soy. Wild-yam salves. These nature-made remedies promise drug-free relief. But are they as squeaky-clean as they seem? And do they work? Our report roots out the truth

BY KATHLEEN MCAULIFFE

DETROL™ Tablets

brand of tolterodine tartrate tablets

What are DETROL Tablets used for?

DETROL Tablets are used to treat a condition called overactive bladder. Patients with overactive bladder have these symptoms: urinary urgency (a strong and sudden desire to urinate), frequent urinations day and night, or urge incontinence (accidental loss of urine caused by a sudden and unstoppable urge to urinate).

What is an overactive bladder?

An overactive bladder is a term for involuntary contractions of the bladder muscle (detrusor).

How does DETROL work?

DETROL blocks contractions of the bladder muscle.

What will DETROL do for me?

In three studies of patients with an overactive bladder, DETROL reduced the number of urinations in two of three studies and increased the amount voided per urination in all three studies compared with placebo (sugar pill).

Who should not use DETROL?

DETROL should not be used by patients with:

- urinary retention (inability to empty the bladder)
- gastric retention (delayed emptying of the stomach)
- uncontrolled narrow-angle glaucoma
- a history of any unusual or allergic reaction to DETROL

What are the precautions associated with use of DETROL?

DETROL should be used with caution by patients with any of the following conditions: significant bladder outflow blockage (slow urinary stream), because of the risk of urinary retention; gastrointestinal blockage disorders, such as pyloric stenosis (a narrowing of the opening where the stomach empties into the small intestine), because of the risk of gastric retention; narrow-angle glaucoma that is being treated; and kidney disease. Patients with liver disease should not receive doses of DETROL greater than 1 mg twice daily. Medicines like DETROL may cause blurred vision. See also, "Can I take DETROL while taking other medicines?" (below). It is not known whether taking DETROL will affect the results of laboratory tests you may undergo for other reasons. In special studies conducted in animals and/or test tubes, the active ingredient in DETROL did not cause an increase in tumors, genetic changes, or changes in fertility.

Can I take DETROL if I am pregnant or nursing?

DETROL has not been studied in pregnant women. Therefore, DETROL should be used during pregnancy only if the potential benefit for the mother justifies the potential risk for the unborn baby. It is not known whether the active ingredient in DETROL passes into human milk. Therefore, mothers who breast-feed should stop taking DETROL until they are no longer nursing.

Can DETROL be used by children?

DETROL has not been studied in children.

Can DETROL be used by elderly patients?

Studies of DETROL included patients up to 91 years of age; nearly half were 65 to 91 years of age. Generally, no overall differences were seen in safety between older and younger patients; therefore, no dosage adjustment is required based on age.

Can I take DETROL while taking other medicines?

As with all prescription medicines, before you take DETROL, it is important for your health care professional to know if you are taking any other medicines. Be sure to mention those that you can buy without a prescription, especially cough/cold medicines, which may also affect urination. Patients taking certain medicines (like erythromycin, Biaxin* [clarithromycin], Sporanox* [itraconazole], Nizoral* [ketoconazole], and miconazole) should not receive doses of DETROL greater than 1 mg twice daily.

What are the most common side effects of DETROL?

Dry mouth was the most common side effect during 12 weeks of treatment with DETROL (reported by 39.5% of those taking 2 mg twice daily compared with 15.9% of those taking a placebo [sugar pill]). Other side effects related to DETROL were indigestion (dyspepsia), headache, constipation, and dry eyes. Eight percent of patients treated with DETROL 2 mg twice daily stopped treatment because of side effects. Dizziness and headache were the most common reasons for stopping treatment with DETROL. DETROL may also cause blurring of near vision, slowing of urinary stream, or inability to urinate. The following events were reported by patients taking DETROL but were not considered treatment-related—back pain; chest pain; fatigue; flu-like symptoms; falls; paresthesia (abnormal sensation); vertigo/dizziness; abdominal pain; diarrhea; flatulence (gas); nausea; vomiting; bronchitis; coughing; pharyngitis; rhinitis (runny nose); sinusitis; upper respiratory tract infection; dysuria (painful urination); frequent urination; urinary retention (inability to urinate) or urination disorder; urinary tract infection; pruritus (itching); rash/erythema (redness); dry skin; arthralgia (painful joints); abnormal vision; nervousness; somnolence (sleepiness); weight gain; hypertension (high blood pressure); and infection, including fungal infection. If you are bothered by side effects, check with your doctor.

How should I take DETROL?

The recommended starting dose of DETROL is 2 mg twice daily for most patients. The dose may be lowered to 1 mg twice daily, if needed. Patients with liver disease and those taking certain medicines (like erythromycin, Biaxin, Sporanox, Nizoral, and miconazole) should not take more than 1 mg twice daily.

Rx only.

US Patent No. 5,382,600
Manufactured for:
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By:
Pharmacia & Upjohn S.p.A.
Ascoli Piceno, Italy

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the female herbal market for Adams, Harkness & Hill, an investment bank in Boston. Others see alternative remedies as a way to get results at a much lower cost than going the medical route. And many women "go natural" to avoid side effects they sometimes experience from traditional HRT.

Topping the list of big sellers, Negrin reports, is dong quai, promoted as an all-purpose feminine tonic, followed by botanicals rich in phytoestrogens (plant-derived estrogenlike substances)—notably, black cohosh, red clover and soy-based products.

To balance the effects of these natural estrogens, women frequently combine such products with progesterone skin creams or wild-yam salves marketed to replenish the body's progesterone supply.

Popular they are—but do these products really work? And are they as gentle and safe as many women think they are? Hordes of users give them rave reviews. What their testimony often lacks, however, is solid scientific research.

Unbeknownst to many consumers, the sale of natural remedies is virtually unregulated, creating an environment in which worthless products and fraudulent claims have flourished. Since 1994, when Congress passed a law permitting natural products to be sold as dietary supplements, they have evaded the rigorous scientific testing required of drugs. Under this law, manufacturers need not prove the safety or efficacy of a supplement. This means companies can sell almost any supplement they want to, as long as its label bears no claim of treating specific diseases.

That's not to imply that all natural products are useless or harmful. Some alternative remedies for menopause are backed by impressive data. The phytoestrogens in several herbs, for example, are chemically similar to female estrogen, and there's mounting clinical evidence that they may ease menopausal complaints. Researchers widely agree these intriguing compounds deserve further study, but they bristle at the notion that such chemicals are somehow safer or better simply because they come from a plant.

"These are potentially potent hormones," stresses Wulf Utian, M.D.,

SOY STORY

Soy products have surged in popularity recently, thanks to their billing as a rich source of phytoestrogens. To many menopausal women, soy represents a safer way to replenish the body's dwindling estrogen supply than the synthetic estrogens often used in hormone-replacement therapy. According to advocates' glowing testimonies, soy

douses hot flashes, boosts cardiovascular health and may even protect against cancer.

Of these claims, soy's cardiovascular benefits are the best documented. In numerous studies, soy protein has been shown to lower LDL—the bad cholesterol—by about 5 to 11 percent, says investigator John Crouse, M.D., of Wake Forest University School of Medicine in Winston-Salem, North Carolina.

Other studies show that soy prevents the oxidation of cholesterol to a form that clogs arteries, and significantly boosts the elasticity of arteries. Ironically, soy's most popular use—to alleviate hot flashes—has been studied the least. In one widely cited Italian investigation of one-hundred-four postmenopausal women aged forty-five to sixty-two, those who received a daily supplement of soy protein had 15 percent fewer hot flashes than did the placebo group.

Whether soy is taken to boost cardiovascular health or to reduce hot flashes, researchers recommend a daily dose of 25 grams of soy protein (roughly the equivalent of three-fourths to one cup of tofu) for best results.

In addition to tofu, other excellent sources of soy include soy milk, roasted soy beans and shakes made from powdered soy protein and fruit juice.

Ph.D., executive director of the North American Menopause Society and chairman of reproductive biology at Case Western Reserve University School of Medicine in Cleveland. "Until they are scientifically scrutinized," he says, "we have no idea how effective or risky they are." Though there is no evidence to confirm it, Utian anticipates that, like the estrogens used in HRT, phytoestrogens in high doses might trigger blood clots or promote cancers of the breast or uterus, especially if taken without the counterbalancing impact of progesterone (a standard component of HRT).

Richard A. Friedman, M.D., director of the psychopharmacology clinic at New York Presbyterian Hospital's Cornell campus in New York City, concurs. "The word 'natural' has a very cuddly romantic appeal to the public, but it is no guarantee of safety," he says. "Cyanide, hemlock and arsenic are natural, too."

Since the manufacture of natural remedies is not monitored by the FDA, there's also the risk that a product may not actually contain what is stated on the label. "Rip-offs happen every day,"

cautions Varro Tyler, Ph.D., a leading expert on natural medicines at Purdue University School of Pharmacy in West Lafayette, Indiana. There *are* high-quality products out there, he hastens to add. "But the many bad ones," he says, "have damaged the reputation of the whole field."

Utian worries, too, about women at high risk for heart disease or osteoporosis who opt for natural cures. "Medicine has so many ways to treat and prevent these conditions, from dietary methods and hormone-replacement therapy to bone-building drugs," he argues. "Why take a chance on an unproven substance?"

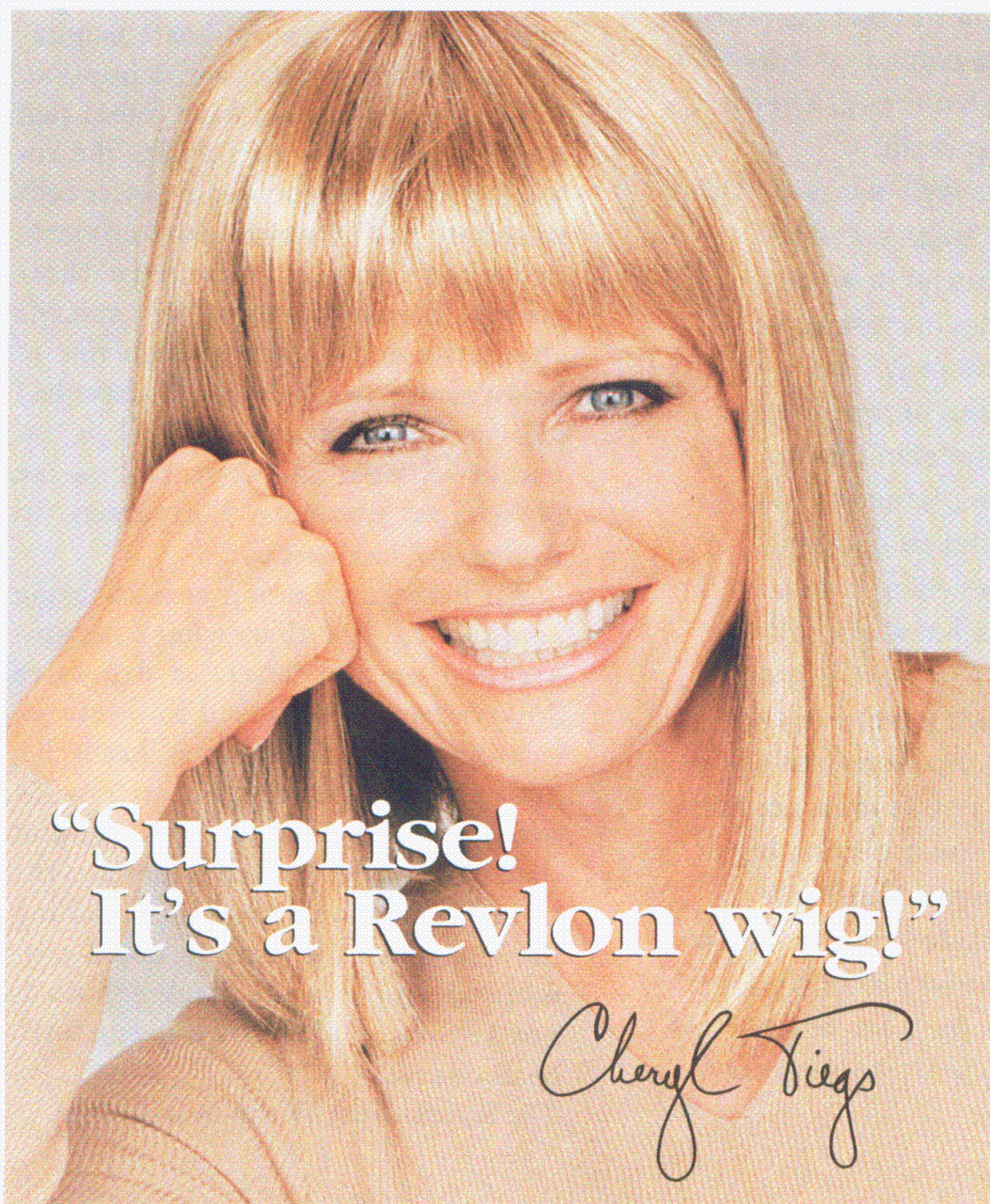
Fans of alternative cures counter that conventional medicines also entail risks, and that the dangers of natural remedies and dietary supplements have been exaggerated. "Many of these botanicals have been used safely by other cultures for centuries," points out Steven Dentali, Ph.D., a pharmaceutical scientist based in Troutdale, Oregon, who serves as a consultant to the natural-products industry. "Do we really need a huge double-blind, placebo-

controlled trial to tell us it's safe to consume soy supplements?"

The bottom line: Weigh the pros and cons carefully. For a woman who has serious menopausal symptoms and can't (or won't) use HRT, an alternative approach may be worth a trial. To minimize the risks, experts advise, she should find a doctor willing to monitor her response to the treatment.

There is no sure way to find contaminant-free products with reliable dosages. But, according to Gale Mahady, Ph.D., an expert on herbal medicines at the College of Pharmacy at the University of Illinois at Chicago, you should look for a reliable manufacturer, i.e., one that has been in the business for several years and has a good reputation. As an additional safeguard, Tyler recommends looking for a product labeled "standardized" and calling the company to ask if it has its own laboratory that analyzes the product's active components. "If they're evasive," he says, "be suspicious."

For more help in navigating the bewildering field of natural menopausal



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remedies, here's a guide to five top-selling products.

DONG QUAI

The promise: This herbal product is known as a blood-purifying tonic in traditional Chinese medicine. Herbalists often prescribe it to treat hot flashes.

The reality: Some animal studies suggest that dong quai acts like an estrogen, and may stimulate endometrial growth—raising the question of potential uterine-cancer risk in humans. But other studies, including human trials, have found no estrogenic properties.

The little scientific evidence available suggests dong quai taken by itself does not ease hot flashes. In a trial conducted at Kaiser Permanente Medical Center in Oakland, California, seventy-one women suffering from hot flashes were given either a placebo or dong quai for twenty-four weeks. In both groups, 30 percent of the women reported a decline in hot flashes. In other words, dong quai was no better than a placebo.

In traditional Chinese medicine, notes a co-author of the study, Bonnie Zell, M.D., dong quai is given in combination with other herbs that may act

with it to produce an effect. Says Zell, "All we can say is that there's no point in taking dong quai by itself."

Intestinal gas was the worst side effect detected by Zell's team. But herbalists caution that dong quai may bring on excessive menstrual bleeding and should not be used by perimenopausal women prone to menstrual flooding. It should be avoided during the first three months of pregnancy, and can also make skin sensitive to sunlight.

The bottom line: Doesn't live up to its reputation.

BLACK COHOSH

The promise: Several extracts of this plant—Remifemin being the best known—are widely sold in Europe and are rapidly gaining popularity here. These preparations are said to provide relief from hot flashes, night sweats, negative mood shifts and vaginal dryness.

The reality: A small but solid base of scientific evidence supports these uses. Half-a-dozen clinical trials confirm that black cohosh relieves menopausal disturbances. In one study in Germany, Remifemin proved superior to estrogen in relieving hot flashes, heart palpitations, sleep disturbances and depression.

More-recent studies have found that Remifemin does not stimulate the reproduction of human breast-cancer cells in culture and can even counter estrogen's tendency to stimulate their growth. "Remifemin might be a suitable alternative for women at high risk of breast cancer or for those who have had it," says Shari Lieberman, Ph.D., a nutrition scientist and instructor at the Nutrition Institute University in Bridgeport, Connecticut.

But herbalists caution against taking amounts higher than what's recommended on the label, as excessive dosages have been linked to dizziness, gastrointestinal disturbance, headache, joint pain and decreased heart rate. In addition, preliminary animal data hint that black cohosh may stimulate the growth of endometrial tissue, raising the question of whether it could promote uterine cancer. Black cohosh is not recommended for anyone with heart disease.

The bottom line: Worth looking into.

THE WILD-YAM SCAM AND "NATURAL" PROGESTERONE CREAMS

Women seeking to restore the body's progesterone supply at menopause are often advised to use wild-yam salves, natural progesterone creams or hybrid products containing both. Users boast of remarkable results, from fewer wrinkles and hot flashes to stronger bones.

When it comes to wild-yam salves, these are wild claims indeed. Wild-yam extract cannot be converted into progesterone by the body, according to herbal experts including Varro Tyler, Ph.D., of Purdue University School of Pharmacy, and Gale Mahady, Ph.D., at the University of Illinois at Chicago's College of Pharmacy.

As for so-called "natural" progesterone creams, many do contain progesterone identical to the body's own, but it doesn't come from a plant—unless a chemical-manufacturing plant qualifies (it's chemically synthesized). And the doses of progesterone can vary widely from cream to cream. In 1995, Aeron

LifeCycles Laboratory, in San Leandro, California, investigated the doses of progesterone contained in these creams. Ten contained insignificant levels of progesterone or none at all, while another twelve contained doses far in excess of what the FDA permits cosmetics to contain.

Physicians widely agree that oral progesterone helps prevent endometrial cancer in women who are also taking estrogen-replacement therapy. It's conceivable—but unproven—that the more-potent skin creams might offer the same protection (though a recent British trial suggests Progest, a top-selling cream on the U.S. market, is not absorbed in a sufficient dose to provide that benefit). There's scant evidence, however, that progesterone by itself relieves hot flashes, smooths wrinkles or increases bone mass.

So if you have a legitimate need for progesterone—namely, to protect the endometrial lining—go to a doctor for a prescription. At least that way you'll know what you're getting.

RED CLOVER

The promise: A preparation of red clover called Promensil is the top-selling natural remedy for menopause in Australia. Now marketed in the U.S. and parts of Europe, the product is said to quench hot flashes and promote cardiovascular health.

The reality: It's still too soon to tell whether Promensil will deliver on its promises. One very small controlled trial done in Australia indicated that Promensil reduced arterial stiffness—a risk factor for heart disease—by 23 percent.

Studies of Promensil's impact on hot flashes have yielded contradictory results: In a trial in Australia, it was no more effective than a placebo. In contrast, all thirty women in a recent study at New York University School of Medicine experienced a decline—often dramatic—in hot flashes. "One woman went from having forty hot flashes a day to zero," reports Lila Nachtigall, M.D., who led the investigation. She cautions that the study lacked a placebo control.

Promensil does not help vaginal dry-

ness, and its effect on breast tissue has yet to be studied.

The bottom line: More research needed to determine whether it helps your heart or eases hot flashes.

VITEX

The promise: Also known as chaste-tree berry, this herb is used for complaints ranging from PMS and breast tenderness to such menopausal disturbances as hot flashes, depression and vaginal dryness. It is also used during perimenopause to prevent spotting between periods, reduce heavy menstrual flow and restore a more-regular cycle until periods cease.

The reality: Human studies conducted in Germany suggest Vitex's main action on the body is to increase progesterone relative to estrogen. Animal studies also show it may inhibit the production of the hormone prolactin, which has been linked to the breast soreness, water retention and depression associated with PMS. Side effects are rare.

The bottom line: May work for PMS, but unproven for menopause symptoms.

VALERIAN

The promise: In Europe, valerian has commonly been prescribed as a mild sedative and sleeping aid since the second century A.D.

The reality: Research shows that valerian apparently binds to the same docking sites in the brain that Valium does, and that it acts slowly on the central nervous system.

Between 1977 and 1996, at least eight studies have corroborated valerian's sedative properties. A review of this research found that valerian took roughly fourteen days to bring about a significant improvement in sleep. In several studies, says Tyler, it promoted as deep and restful a sleep as did Valium, but had the advantage of not being addictive or causing a groggy hangover the next day. And valerian has a reputation for being safe, when it is taken in proper doses. Valerian could, in theory, help menopausal women who are trying to restore a normal sleep cycle.

The bottom line: A relatively safe natural antidote to insomnia. ■

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