Menopause denotes the cessation of menstruation in women. It usually occurs between the ages of 48 and 52. Common symptoms associated with menopause include: hot flashes, thinning of the vaginal lining, and psychological symptoms such as depression, anxiety, and forgetfulness. The traditional medical view of menopause is more of a disease rather than a normal physiological process. Current medical treatment of menopause primarily involves the use of hormone replacement therapy (HRT) featuring the combination of estrogen and progesterone.

Q Are there concerns associated with HRT?
A The cancer-causing potential of HRT is a real and serious concern. More than 30 studies have been performed to determine the risk of HRT on cancer. Unfortunately, despite intense investigation, these studies have not provided clear-cut answers. The bottom line is that nobody really knows for sure what impact HRT has on cancer, but there is enough evidence to warrant concern.

Q To what cancer is HRT most closely linked?
A Breast cancer, which is already the most common cancer in women. Current estimates are that one in nine women in the United States will develop breast cancer. Since estrogens play a critical role in the development of most breast cancers, it only makes sense that additional estrogens may promote breast cancer. Several studies of post-menopausal women taking estrogen have shown an increased risk for breast cancer. When all the studies are examined collectively, experts have calculated that estrogen replacement therapy is associated with a 1% to 30% increase in the risk of breast cancer. Most of the positive studies were conducted in European countries. In comparison, only a few studies in the United States have shown HRT increases the risk of breast cancer.

Q Why is there such a difference in the results of American and European studies?
A These results raise some interesting questions. Are American researchers biased? Is the failure of some studies in American women to show an increased risk for breast cancer due to the fact that American women are already at high risk for breast cancer? And why are American researchers so defensive about the positive findings in the European studies?

The answers of these questions may reflect the fact that the United States medical establishment has enthusiastically recommended estrogen and HRT for many years. No researcher or physician wants to admit that a
drug that they have so enthusiastically recommended is now linked to cancer. When data does come out suggesting an association between HRT and cancer, it is downplayed. For example, when a 1995 follow-up analysis of the 1990 United States Nurses Health Study demonstrated a 40% increase in breast cancer among women between 50 and 64 years of age who had used HRT for five or more years, and a 70% increase in risk in women between 65 and 69 years, physicians and popular media reports urged women not to overreact. Women were instructed to wait for confirmation from the larger, more comprehensive Women's Health Initiative being conducted by the National Institutes of Health that will be available in the year 2007!

Q What are the benefits of HRT?
A The benefits include relief of hot flashes and other menopausal symptoms, a significant reduction in osteoporosis, and a possible reduction in cardiovascular disease. Before you get too excited about these beneficial effects, it is important to note that dietary, exercise, and lifestyle factors have also been shown to offer identical benefits without the risks. The bottom line is that long-term HRT is not justified in most women because the risks outweigh the benefits. A natural approach offers significant advantages.

Q What is the natural alternative to managing menopause?
A The most widely used and only thoroughly studied natural approach to menopause is black cohosh (*Cimicifuga racemosa*) standardized to contain 1 mg of triterpenes, calculated as 27-deoxyactein, per tablet. Clinical studies have shown black cohosh to relieve not only hot flashes, but also depression and vaginal atrophy. The VGA, the German equivalent to the FDA in the United States, includes no contraindications or limitations of use for black cohosh in tumor patients. Therefore, black cohosh offers a suitable natural alternative to HRT, especially where HRT is contraindicated, e.g., in breast cancer among women overreact. Women were instructed to wait for confirmation from the larger, more comprehensive Women's Health Initiative being conducted by the National Institutes of Health that will be available in the year 2007!

Q What do the clinical studies on black cohosh indicate?
A The clinical documentation on black cohosh is exceptional. Let's review in detail the results from five human studies.

STUDY 1: A large open study
Black cohosh produced clear improvement of menopausal symptoms in more than 80% of patients within six to eight weeks in a large open study employing 131 doctors and 629 female patients. Both physical and psychological symptoms improved. Most patients reported noticeable benefits within four weeks of beginning black cohosh therapy. After six to eight weeks, complete resolution of symptoms was achieved in a high number of patients. Black cohosh was very well tolerated, as there was no discontinuation of therapy and only 7% of patients reported mild transitory stomach complaints.

STUDY 2: A controlled study of black cohosh vs. premarin or valium
In this study, 60 patients were given either black cohosh, conjugated estrogens (Premarin; 0.625 mg daily), or diazepam (Valium; 2 mg daily) for 12 weeks. Results from standard indexes of menopausal symptoms indicated a clear advantage of black cohosh over both drugs. Black cohosh's effect on relieving the depressive mood and anxiety associated with menopause was far superior to either diazepam or conjugated estrogens. One of the most utilized assessments in clinical studies in menopause is the Kupperman Menopausal Index. This quantitative assessment of menopausal symptoms is achieved by grading in severity: Severe=3, Moderate=2, Mild=1, Not present=0. Symptoms assessed:

- Hot flashes
- Depressive moods
- Profuse perspiration
- Feelings of vertigo
- Sleep disturbances
- Loss of concentration
- Headache
- Joint pain
- Nervousness/irritability
- Heart palpitation
- Heart palpitations

The results of the Kupperman Menopausal Index from this trial clearly demonstrate black cohosh's superiority over conjugated estrogens and diazepam, especially when safety and side effects are taken into consideration. Effect on Kupperman Menopausal Index

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Beginning</th>
<th>12 weeks</th>
</tr>
</thead>
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<tr>
<td>Black cohosh</td>
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<td>14</td>
</tr>
<tr>
<td>Conjugated estrogens</td>
<td>35</td>
<td>16</td>
</tr>
<tr>
<td>Diazepam</td>
<td>35</td>
<td>20</td>
</tr>
</tbody>
</table>

STUDY 3. A double-blind study of black cohosh vs. premarin or placebo
Eighty patients were given either black cohosh, conjugated estrogens (0.625 mg daily), or placebo for 12 weeks. Black cohosh produced better results in the Kupperman Menopausal Index, the Hamilton anxiety test, and the vaginal lining than estrogens or placebo. The number of hot flashes experienced each day dropped from an average of five to less than one in the black cohosh group. In comparison, the estrogen group dropped from 5 to only 3.5. Even more impressive was the effect of black cohosh on the vaginal lining. While conjugated estrogens as well as the placebo produced little effect, a dramatic increase in the number of superficial cells was noted in the black cohosh group.
STUDY 4. A double-blind study of black cohosh vs. placebo

In a double-blind study of 110 women, black cohosh was shown to exert significant improvements in menopausal symptoms.

STUDY 5. Randomized study in partial hysterectomy

In a study of 60 women under the age of 40 who had hysterectomies leaving at least one intact ovary, the women were given either black cohosh, estradiol (1 mg daily), conjugated estrogens (1.25 mg daily), or an estrogen-progestin combination (Trisequens, one tablet daily). Although the hormone therapies produced better results as determined by a modified Kupperman's Menopausal Index, black cohosh still displayed significant effects in relieving the symptoms of surgical menopause. The results indicate that black cohosh can be a suitable alternative to estrogens in women having partial, and possibly even complete, hysterectomies.

**Q How long does it take to see benefits with black cohosh?**

A Most women experience significant improvement in symptoms within four to eight weeks.

**Q Can black cohosh be used by women with a history of breast cancer?**

A Yes. The VGA includes no contraindications or limitations of use for black cohosh. Since black cohosh shows some, albeit weak, estrogenic activity, researchers have sought to determine its effect on established breast tumor cell line whose growth in vitro depends on the presence of estrogens. The results from these experiments show no stimulatory effects, but rather inhibitory effects.

The current data indicates that black cohosh offers a suitable natural alternative to HRT for menopause, especially where HRT is contraindicated, such as for women with a history of estrogen-dependent cancer, unexplained uterine bleeding, liver and gallbladder disease, pancreatitis, endometriosis, uterine fibroids, and fibrocystic disease.

**Q Since black cohosh is a phytoestrogen, shouldn't natural progesterone be used in conjunction?**

A No, it is not necessary. First of all, it is necessary to make an important distinction. Although black cohosh is considered a phytoestrogen, its pharmacological activity is quite different than estrogen. The reason progesterone was originally used in conjunction with estrogen is that when estrogen was used alone (unopposed), it significantly (up to 13 times) increased the risk of endometrial cancer. In contrast to estrogens, black cohosh exerts no effect on the endometrium. Specifically, both human and animal studies have shown that black cohosh does not produce endometrial thickening.

**Q Does black cohosh affect bone resorption?**

A One of the most publicized effects of estrogen is its role in maintaining bone health and preventing osteoporosis. While there is experimental and epidemiological evidence that phytoestrogens prevent osteoporosis and reduce bone resorption, at this time there are no long-term studies demonstrating black cohosh can prevent or improve osteoporosis. However, based on black cohosh's mechanism of action and long-term clinical experience, many experts believe it will be shown to positively influence bone resorption.

**Q What is the most effective dosage?**

A The newest recommendation of the German Kommission E is a 20-mg tablet, standardized at 27-deoxyactein, in the morning, and a 20-mg tablet in the evening. The Kommission E is the world standard for regulating herbal products.

**Q How long can black cohosh extract be used?**

A Black cohosh has been used in Germany since 1956 and has a remarkable safety record. No serious side effects have ever been reported. Although the Kommission E monograph has recommended that treatment with black cohosh be limited to six months (the standard recommendation for HRT as well), this recommendation was made prior to more recent detailed toxicology studies. Based on currently available data, black cohosh is appropriate for long-term continued use if so desired.

The no-effect dosage in studies in a six-month chronic toxicity study in rats was at 1,800 mg/kg body weight—or roughly 90 times the human therapeutic dose. A six-month toxicological study in rats is comparable to an unlimited treatment time in humans. Detailed toxicology studies have also been performed on black cohosh. No teratogenic, mutagenic, or carcinogenic effects have been noted.

**Summary**

Black cohosh has been shown to produce symptomatic relief comparable to that of HRT without the risk of serious side effects. In regards to black cohosh, the following can be stated: It is a safe and effective alternative to HRT.

Black cohosh is effective in the relief of all menopausal symptoms:

**Physical:** Hot flashes, night sweats, headaches, heart palpitations, and vaginal atrophy.

**Psychological:** Depression, anxiety, nervousness, sleep disturbances, and decreased libido.

**Dosage:** One 20-mg tablet twice daily.