

# Menopause SAP

Science-based formula for menopause support

**Menopause SAP** contains a combination of four evidence-based standardized herbal extracts that can help in the management of menopause-related symptoms and profoundly improve pre-, peri-, and postmenopausal quality of life.\* Menopause, the period of time in a woman's life when menstruation ceases, is often accompanied by troublesome symptoms, including hot flashes, vaginal dryness, night sweats, and sexual dysfunction.\* A substantial decline in the quality of life and increased susceptibility to psychological problems is usually observed during peri- and postmenopause.\* Interventions that decrease the severity and frequency of these menopausal symptoms are likely to improve a person's wellbeing and quality of life. Herbal medicine offers an effective and safe alternative to the conventional therapies for alleviation of menopausal symptoms.\* **Menopause SAP** can help mitigate the severity and frequency of hot flashes, improve sleep quality, foster mental wellbeing, and improve menopause-associated sexual dysfunction.\*

## SUPPLEMENT FACTS

Serving Size: 1 Capsule

	Amount Per Serving	% Daily Value
Black cohosh ( <i>Actaea racemosa</i> ) rhizome extract, 2.5% triterpene glycosides	20 mg	**
Maca ( <i>Lepidium meyenii</i> ) powder, providing 0.4% macamides and macaenes	130 mg	**
St. John's wort ( <i>Hypericum perforatum</i> ) herb top extract (8:1)	140 mg	**
Rhapontic rhubarb ( <i>Rheum rhaponticum</i> ) root extract, 0.77% rhaponticin	150 mg	**

‡ Percent Daily Values are based on a 2,000-calorie diet.

\*\*Daily Value not established

**Other ingredients:** Gluten, soy, wheat, eggs, dairy, yeast, citrus, preservatives, artificial flavor or color, starch, or sugar.

**This product is non-GMO and vegan friendly.**

**Contains no:** Gluten, soy, wheat, eggs, dairy, yeast, citrus, preservatives, artificial color and flavor.

**Menopause SAP** contains 60 capsules per bottle.

## DIRECTIONS FOR USE

**Adults:** Take 1 capsule twice daily or as directed by your healthcare practitioner. Consult a healthcare practitioner for use beyond 3 months. Use for a minimum of 1 week to see beneficial effects.

## INDICATION

**Menopause SAP** can:

- Help reduce the severity of hot flashes and night sweats.\*
- Be used to maintain mood balance.\*
- Be used to enhance sleep quality.\*
- Be used to improve vaginal dryness and sexual dysfunction.\*

## CAUTIONS AND WARNINGS

Consult a healthcare practitioner if symptoms persist or worsen. Consult a healthcare practitioner prior to use if you have a liver disorder or develop symptoms of liver trouble; if you are taking antianxiety medications, seizure medications, antihistamines, bronchodilators, muscle relaxants, and/or opiates. Do not use if you are pregnant or if you are taking anticancer medications, blood thinners, antidepressants (e.g. selective serotonin reuptake inhibitors [SSRI]), anti-HIV agents, cardiovascular medications, immunosuppressants, and/or contraceptive medications. Avoid prolonged exposure to sunlight, ultraviolet light (UV), or UV therapy. Hypersensitivity, such as an allergy, has been known to occur; in which case, discontinue use. Some people may experience mild gastrointestinal disturbances, nausea, restlessness and/or headaches.

## PURITY, CLEANLINESS, AND STABILITY

All ingredients listed for each **Menopause SAP** lot number have been tested by an ISO 17025-accredited third-party laboratory for identity, potency, and purity.

**\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Scientific Advisory Panel (SAP):  
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## MENOPAUSE EFFECTS ON HEALTH AND QUALITY OF LIFE

Menopause marks the permanent cessation of menstruation and the end of the reproductive period. It usually occurs around a mean age of 51 years, with most women experiencing menopause within a range of 40 to 58 years of age.<sup>[1, 2, 3]</sup> The period of transition to menopause, often defined as “perimenopause,” is characterized by irregular menstruation during the preceding 12 months before menopause. “Postmenopause” is the absence of menstruation for more than 12 months.<sup>[1, 2, 3]</sup> During the period of transition to menopause, a number of events occur, leading to the reduction in ovarian activity. Such changes could be a result of physiological menopause due to the aging ovaries and their decreased responsiveness to follicle-stimulating hormone (FSH) and luteinizing hormone (LH).<sup>[1, 3]</sup> These physiological changes result in fewer ovulations, and in decreasing amounts of circulating progesterone and estrogen. Another type of menopause, referred to as “iatrogenic menopause,” stems from medical intervention, such as oophorectomy (removal of the ovaries), chemotherapy, and pelvic irradiation.<sup>[3]</sup>

The common types of symptoms usually reported during menopause include vasomotor symptoms (hot flashes and sweating), vulvovaginal atrophic symptoms such as vaginal atrophy, vaginal dryness, impaired sexual function, as well as mood and sleep disturbance.<sup>[1, 2, 4]</sup> These symptoms typically last for an average duration of 3.5 years; however, they can range from five months to 10 years, and with varying degrees of severity.<sup>[1, 2, 4]</sup> Notably, postmenopausal women are highly susceptible to the risk of osteoporosis development, with increasing risk as they age.<sup>[1, 2, 4]</sup> This perimenopausal period may be also associated with a significant decline in quality of life.<sup>[1, 4]</sup> This includes a decline in perceived physical health, nervous and emotional state, self-confidence, ability to manage work life, and decision-making.<sup>[1, 4]</sup>

## HERBALS IN THE MANAGEMENT OF MENOPAUSE SYMPTOMS

It is reported that about two-thirds of perimenopausal women develop symptoms related to menopausal transition. Among them, approximately 10–25% of women seek an alternative treatment from their healthcare provider, due to dissatisfaction with conventional medical therapies for their symptoms.<sup>[2, 5]</sup> Hormone therapy represents the first line of treatment for vasomotor symptoms.<sup>[5]</sup> However, following the published results from the Women's Health Initiative, botanical and dietary supplement-based therapy is more preferred over exogenous hormone therapy for the management of menopausal symptoms.<sup>[5, 6]</sup> Herbal-based treatments have been reported to be effective and safe, either alone or in combination, for the alleviation of menopausal symptoms.<sup>[1, 2, 5]</sup> The key plant-based therapies are reviewed in detail below.

## BLACK COHOSH, 2.5% TRITERPENE GLYCOSIDES

Black cohosh (*Actaea racemosa* or *Cimicifuga racemosa*), also known as bugbane and rattlesnake, is a tall-stemmed plant native to Canada and eastern US, and was traditionally used by Native Americans to treat a number of maladies including menstrual irregularities and child birth.<sup>[1, 7]</sup> Black cohosh rhizome contains a number of biologically active constituents such as the triterpene glycosides actein and cimicifugoside, fatty acids, resins, caffeic acids, isoflavonic acids and isoflavones, and  $N_{\alpha}$ -methylserotonin.<sup>[1, 7]</sup> The active compounds of black cohosh mostly behave as neurotransmitters like 5-hydroxytryptamine (5-HT) and  $\gamma$ -aminobutyric acid (GABA), with an ability to stimulate dopaminergic-2 (D2) receptors.<sup>[7]</sup> This dopaminergic effect may not only oppose prolactin, which may improve libido, but may also improve bone mineral density by increasing osteoblast activity and hence, reduce bone metabolism and bone loss. These skeletal effects are not dissimilar to those induced by estrogen.<sup>[7]</sup> The triterpene glycosides of black cohosh have been reported to reduce circulating levels of LH, thereby mitigating some of the undesirable symptoms of menopause.<sup>[7]</sup>

In a recent randomized, double-blind, placebo-controlled study in postmenopausal women for a 6-month duration, black cohosh treatment (two tablets per day of standardized isopropanolic extract, containing extract of 20 mg crude drug per tablet) resulted in significant increase in sleep efficiency and decreased wake after sleep onset (WASO) duration compared to the placebo. Black cohosh treatment also improved the polysomnography and the Pittsburgh sleep quality indices (PSQI).<sup>[8]</sup> In another study, a standardized isopropanolic black cohosh extract (40 mg crude drug per day) was found to be more effective and an appropriate choice in alleviating menopausal symptoms in women with uterine fibroid compared to Tibolone.<sup>[9]</sup> Also, black cohosh (6.5 mg of dried root extract daily) significantly improved the Greene climacteric scale (GCS) subscale scores (vasomotor, psychiatric, physical, and sexual symptoms) compared to the control group in a placebo-controlled, randomized clinical trial in postmenopausal women.<sup>[10]</sup> The World Health Organization (WHO) and the North American Menopause Society recognize the use of black cohosh as a treatment option for women with menopause-related symptoms.<sup>[1]</sup>

## Safety

Black cohosh administration has been reported to be safe for the treatment of menopausal symptoms by many studies and recent meta-analyses.<sup>[1, 2, 7, 8, 9, 10]</sup> Adverse events associated with black cohosh were rare, mild, and reversible, and there is insufficient evidence of a causal relationship between these side effects and black cohosh.<sup>[1, 7]</sup>

## MACA ROOT

Maca (*Lepidium meyenii*) is an Andean plant of the mustard family, widely grown in many South American countries.<sup>[11, 12]</sup> Maca has been traditionally used for centuries in the Andes as an adaptogenic plant to manage anaemia, infertility, and female hormone balance.<sup>[11, 12]</sup> Maca root contains many potentially bioactive ingredients including macaridine, macamides, maceane, glucosinolates, maca alkaloid, sterols, fatty acids, minerals, and vitamins.<sup>[11]</sup> In a placebo-controlled study, maca administration (2 g/d of gelatinized maca root powder) in early postmenopausal women resulted in decreases in follicle-stimulating hormone (FSH) and increases in luteinizing hormone (LH) production compared to the placebo.<sup>[12]</sup> Maca administration has been also shown to improve menopausal symptoms.<sup>[12, 13]</sup> In a double-blind, placebo-controlled study of 30 premenopausal and 12 postmenopausal women, significant improvement in antidepressant-induced sexual dysfunction was observed after maca root administration (3 g/d) compared to the placebo.<sup>[14]</sup>

## Safety

Maca has been reported to have low toxicity (LD<sub>50</sub> for mice is > 16.3 g/kg). In both in vivo and in vitro studies, regardless of extraction method, maca root extracts have demonstrated no toxicity and are well-tolerated.<sup>[11, 13, 14]</sup>

## ST JOHN'S WORT (HYPERICUM) EXTRACT, 0.3% HYPERICIN

St John's wort (*Hypericum perforatum* L.), also known as *Hypericum*, is a herbaceous perennial plant native to Europe and Asia, now naturalized into the United States after its introduction. The major active constituents are considered to be hypericin and hyperforin; other bioactive components such as flavonoids and tannins are also present.<sup>[15]</sup> A recent meta-analysis reported that St John's wort extracts and its combination with herbs were effective in improving the symptoms of menopause when compared to the placebo. Also, St John's wort extracts exhibited fewer side effects for the treatment of menopausal women.<sup>[16]</sup> In a randomized, double-blind, placebo-controlled study, administration of St John's wort extract (oral drops containing 0.2 mg/mL of hypericin) three times a day was found to significantly reduce the severity, frequency, and duration of hot flashes in premenopausal, perimenopausal, and postmenopausal women when compared to the placebo after treated for 8 weeks.<sup>[17]</sup> A systematic analysis revealed that a combination of St John's wort and black cohosh proved to be effective for the treatment of menopausal symptoms.<sup>[16]</sup>

## Safety

Data from various studies suggest that St John's wort is well-tolerated. Adverse effects are generally mild. In placebo-controlled trials, the frequency of adverse effects with St John's wort is similar to that for placebo. Potential interactions between St John's wort extracts and certain prescribed medicines including warfarin, cyclosporine, theophylline, and digoxin may exist; hence, it is usually recommended to seek professional advice before consuming St John's wort so that appropriate dose adjustment of conventional treatment is made.<sup>[15]</sup>

## RHAPONTIC RHUBARB ROOT EXTRACT, 0.77% RHAPONTICIN

Extracts from the roots of rhapontic rhubarb (*Rheum raphaniticum*) has long been prescribed for alleviating menopause-related complaints, including anxiety, in peri- and postmenopausal women.<sup>[9]</sup> The plant is also known as Siberian rhubarb, originating from Central Asia. The root extract contains rhaponticin and desoxyrhaponticin, as well as their aglycones rhapontigenin and desoxyrhapontigenin, which are structurally similar to resveratrol.<sup>[9]</sup> In a multicentre, prospective, randomized, double-blind, placebo-controlled clinical trial with 109 perimenopausal women with menopause complaints for 12 weeks, rhapontic rhubarb extract (1 enteric-coated tablet per day containing 4 mg of the extract) administration resulted in significant mitigation of menopausal symptoms.<sup>[20]</sup> Specifically, the treatment with this extract after 12 weeks significantly reduced the Menopause Rating Scale II symptoms compared to the placebo. After four weeks of treatment, the number and severity of hot flashes were decreased. After 12 weeks, the overall menopause-related quality of life was significantly better in women provided the extract compared to those who received placebo.<sup>[20]</sup>

## Safety

No adverse events have been observed in human applications of rhapontic rhubarb extracts, even in long-term efficacy studies for a duration 48 and 96 weeks, and the extract was found to be safe and well-tolerated.<sup>[19, 20, 21]</sup> However, more studies need to be conducted to confirm the safety of rhapontic rhubarb extracts.

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