# **Chastetree+ SAP**

### Science-based formulation for menstrual cycle support

**Chastetree+ SAP** is a synergistic blend of chasteberry, *Ginkgo biloba*, and vitamin B<sub>6</sub>, used to help regulate menstrual-cycle concerns. This formulation assists in relieving negative symptoms associated with the menstrual cycle such as irregular menstruation, mood imbalances, breast tenderness, irritability, and menstrual cramping. Symptoms such as hot flashes, memory changes, and insomnia associated with perimenopause and menopause may also be improved with use of **Chastetree+ SAP**.

## **ACTIVE INGREDIENTS**

#### Each vegetable capsule contains:

Chasteberry ( <i>Vitex agnus-castus</i> ) fruit,	
0.5% agnusides and 0.6% aucubins 60	0 mg
Ginkgo biloba leaf, 24% flavones and 6% terpenes 4	0 mg
Vitamin B <sub>6</sub> (pyridoxal-5'-phosphate) 5	0 mg

**Other ingredients:** Vegetable magnesium stearate and silicon dioxide in a non-GMO vegetable capsule composed of vegetable carbohydrate gum and purified water.

#### This product is non-GMO.

**Contains no:** Gluten, soy, wheat, eggs, dairy, yeast, citrus, preservatives, artificial flavour or colour, starch, or sugar.

Chastetree+ SAP contains 60 capsules per bottle.

## **DIRECTIONS FOR USE**

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

## **INDICATIONS**

**Chastetree+ SAP** may increase a shortened luteal phase and improve progesterone levels, and helps:

- $\cdot~$  Relieve symptoms associated with premenstrual syndrome (PMS).
- · As a hormone normalizer to help stabilize menstrual cycle irregularities.
- Relieve symptoms associated with menopause such as hot flashes, memory, and learning decline.

and may help:

Normalize elevated prolactin secretion.

## **CAUTIONS AND WARNINGS**

Consult a healthcare practitioner prior to use if you are taking medications for diabetes, high blood pressure, or seizures; if you are taking hormone-containing medications such as progesterone preparations, oral contraceptives, or hormone replacement therapy. Consult a healthcare practitioner if symptoms persist or worsen.

**Contraindications:** Do not use if you are taking health products that affect blood coagulation (e.g. blood thinners, clotting factor replacements, acetylsalicylic acid, ibuprofen, fish oils, vitamin E), as this may increase the risk of spontaneous bleeding. Do not use if you are pregnant, breastfeeding or attempting to conceive unless you have consulted with a healthcare practitioner.

## **PURITY, CLEANLINESS, AND STABILITY**

All ingredients listed for all **Chastetree+ SAP** lot numbers have been tested by a third-party laboratory for identity, potency, and purity.



351, Rue Joseph-Carrier, Vaudreuil-Dorion, Quebec, J7V 5V5 T 1 866 510 3123 • F 1 866 510 3130 • nfh.ca

NFH

Chastetree+ SAP

Menstrual cycle Support Soutien du cycle menstruel

NPN 80066185

**60 CAPSULES** 

Scientific Advisory Panel (SAP):

adding nutraceutical research

to achieve optimum health

lents have been tested by a third-party laboratory for identity, potency, and purity grédients ont été testés par un laboratoire externe pour l'identité, la puissance et la pureté

## **Research Monograph**

Women often struggle with hormonal imbalances. These imbalances can present as concerns such as irregular menstrual cycles, breast tenderness, menstrual cramping and pain, mood fluctuations, hot flashes or night sweats, and insomnia. Premenstrual syndrome (PMS) is an extremely common condition that most menstruating women experience at some point during their reproductive years.<sup>[1]</sup> In about 10% of women, the symptoms can become incapacitating.<sup>[1]</sup> Chastetree berry (Vitex agnus-castus), Ginkgo biloba, and vitamin B<sub>6</sub> have all been thoroughly researched and have demonstrated a positive improvement in several symptoms associated with hormonal imbalances.

#### **GINKGO BILOBA**

Being that PMS is so common and a chronic situation, it is important to pay attention to the side effects of common pharmaceutical interventions.[1] Researchers have focused on herbal intervention because of a more favourable therapeutic approach, with fewer side effects.[1]

One study looked specifically at the impact of Ginkgo biloba on the symptoms of PMS.<sup>[1]</sup> In a single-blind, randomized, placebo-controlled trial, women with PMS living in dormitories at a medical university entered this study.<sup>[1]</sup> 90 students with a verified PMS diagnosis were randomly assigned to either the active group supplemented with Ginkgo tablets (with 40 mg leaf extract, three times per day), or to the placebo group.<sup>[1]</sup> Women supplemented their assigned medicines from day 16 of their menstrual cycle to day 5 of the following menstrual cycle.[1] Data was collected using daily symptom-rating forms. Researchers found that there was a significant decrease in overall severity of both psychological and physical symptoms in both the Ginkgo (23.8%) and placebo (8.74%) groups.<sup>[1]</sup> However, the mean decrease was significantly more in the Ginkgo group compared to the placebo group.<sup>[1]</sup> Researchers concluded that Ginkgo biloba can reduce the severity of PMS symptoms but suggested further research on efficacy and safety of various doses and treatment duration are required.[1]

In a controlled, multicentre, double-blind study, the efficacy of standardized Ginkgo biloba extract in treating congestive symptoms of premenstrual syndrome (PMS) was evaluated.<sup>[2]</sup> Women suffering for at least three consecutive cycles from congestive premenstrual troubles for a minimum of seven days premenses were admitted into the trial.<sup>[2]</sup> Women were then observed for one menstrual cycle to confirm the diagnosis, then for the following two cycles they were given either placebo or Gingko biloba from the 16th day of the cycle until the 5th day of the next cycle.[2] A double evaluation method was used, which included a daily rating scale by the patients, as well as assessments by the practitioner during the visits at the premenstrual phase before and after the two treatment cycles.<sup>[2]</sup> Researchers found that Ginkgo biloba was effective against congestive symptoms of PMS, with breast symptoms and neuropsychological symptoms in particular showing the most improvement versus placebo.<sup>[2]</sup> Researchers concluded that Ginkgo biloba is of therapeutic interest in the treatment of PMS.[2]

#### VITEX AGNUS-CASTUS (VAC OR VITEX) OR CHASTEBERRY

Vitex agnus-castus (VAC), also known as chasteberry, has been shown in scientific literature to be an effective treatment for irregular menstrual cycles, cyclical mastalgia (breast tenderness), and other symptoms of premenstrual syndrome.<sup>[3]</sup> In a multicentre, double-blind, placebo-controlled trial, researchers attempted to identify an effective dosing strategy for VAC extract Ze 440.<sup>[3]</sup> Over a period of three menstrual cycles, 162 women with PMS were randomly assigned to one of four groups, receiving either placebo or one of three doses of the extract Ze 440; either 8, 20, or 30 mg per day over three menstrual cycles.<sup>[3]</sup> The symptoms of PMS and their severity were assessed by patients using visual analog scales for irritability, mood alteration, anger, headache, bloating, and breast fullness.<sup>[3]</sup> All treatments were well-tolerated, and the total symptom score improvement was significantly higher in both the 20 mg and 30 mg groups compared to the 8 mg and placebo groups.<sup>[3]</sup> Researchers concluded that VAC was effective in relieving symptoms equally at 20 mg and 30 mg; therefore, 20 mg would be the preferred daily dose.<sup>[3]</sup>

In another trial, researchers wanted to determine the efficacy of VAC in the treatment of Chinese women struggling with moderate to severe PMS.<sup>[4]</sup> Participants were randomly assigned to receive either one tablet of VAC [containing 4.0 mg of dried ethanolic (70%) extract of VAC (corresponding to 40 mg of herbal drug)] or placebo daily for three cycles.<sup>[4]</sup> Symptoms were tracked using a daily rating scale of four symptoms (negative affect, water retention, food cravings, and pain).<sup>[4]</sup> The premenstrual syndrome diary (PMSD) sum score decreased from 29.38 ± 7.63 to 4.8 ± 5.76 by the third cycle in the

treatment group.<sup>[4]</sup> The sum score decreased from 28.76 ± 8.23 to 11.79 ± 11.78 in the placebo group.<sup>[4]</sup> There was a significant difference in PMSD sum score of water retention and negative affect between the two groups, and the efficacy rate (defined as a sum score decrease of 60%) in the treatment group was significantly higher than that in the placebo group at the third treatment cycle.<sup>[4]</sup> Researchers concluded that VAC extract is effective in treating moderate to severe PMS in Chinese women.[4]

An objective systematic review evaluated the evidence for the efficacy and safety of Vitex extracts from randomized controlled trials investigating women's health.<sup>[5]</sup> Twelve trials were included in the review, of which eight investigated premenstrual syndrome, two investigated premenstrual dysphoric disorder, and two investigated latent hyperprolactinaemia.<sup>[5]</sup> For premenstrual syndrome, five of the six trials found Vitex superior to placebo, whereas one trial found Vitex to be superior to pyridoxine and one trial found Vitex to be superior to magnesium oxide.[5] In latent hyperprolactinaemia, one trial found Vitex to be superior to placebo for reducing TRH-stimulated prolactin secretion, normalizing a shortened luteal phase, increasing midluteal progesterone and  $17\beta$ -oestradiol levels.<sup>[5]</sup> The second trial found Vitex comparable to bromocriptine for reducing serum prolactin levels and ameliorating cyclic mastalgia.<sup>[5]</sup> The two studies looking at premenstrual dysphoric disorder reported differing results. Both compared Vitex and fluoxetine, with one study reporting the two treatments to have equivalent efficacy, whereas the second found fluoxetine treatment superior to Vitex.[5] Researchers noted that the methodological quality of the studies varied, but in general, all were moderate to high quality.<sup>[5]</sup> Results from the trials do demonstrate that Vitex is a viable treatment for PMS, premenstrual dysphoric disorder, and latent hyperprolactinaemia.[5]

Phytoestrogens have more recently been proposed as a potential preventative agent to help preclude menopause-related cognitive decline.<sup>[6]</sup> In a rat study, animals were ovariectomized and randomly divided into four groups:<sup>[6]</sup> a control group, two groups who received 8 or 80 mg/kg Vitex agnus-castus ethanolic extract orally, and the last group whom received 40 μg/kg of estradiol valerate.<sup>[6]</sup> Learning and memory were evaluated using a step-through passive avoidance test.<sup>[6]</sup> Results were derived by real-time PCR measuring hippocampal estrogen receptor (ER).<sup>[6]</sup> Results demonstrated that both estradiol and VAC had better performance than the control group.<sup>[6]</sup> It was also found that the treatment groups had increased the hippocampal mRNA level of ER and prevented the decrease in uterine weight of ovariectomized rats.<sup>[6]</sup> Researchers concluded that VAC extract improves learning and memory in ovariectomized rats, possibly via an increase in ER gene expression in the hippocampal formation.<sup>16</sup>

#### PYRIDOXINE (VITAMIN B,)

Researchers compared the medication bromocriptrine (2.5 mg twice per day) to pyridoxine (100 mg/d) and to a control group for women suffering with PMS.<sup>[7]</sup> A premenstrual score was recorded based on 20 PMS symptoms for each participant and then the patients were divided into three groups.<sup>[7]</sup> After three months, results showed that there was a significant reduction in the mean premenstrual symptom score in both treatment groups, but not the control group.[7] Researchers concluded that both treatments are effective for the treatment of PMS, but pyridoxine showed a significantly higher response rate and fewer incidence of side effects than bromocriptine.[7

A second study explored the effects of vitamin B<sub>6</sub> on PMS combined B<sub>6</sub> with magnesium (Mg), or gave magnesium on its own, or placebo.[8] Patients were randomly assigned to one of the three groups for a two-month treatment trial period and pre- and posttest results were compared.[8] After the intervention, there was a decrease in the mean score of PMS in all three groups.<sup>[8]</sup> The decrease was greatest in the Mg+B<sub>6</sub> group, and lowest in the placebo group.<sup>[8]</sup> This led researchers to conclude that Mg plus vitamin B, has the greatest effect on PMS symptoms.[8]

#### REFERENCES

- 2
- CYPERCIPCED Orgoli, G., et al. "A randomized, placebo-controlled trial of Ginkgo biloba L. in treatment of premenstrual syndrome." Journal of Alternative and Complementary Medicine Vol. 15, No. 8 (2009): 845–851. Tamborini, A. and R. Taurelle. "[Value of standardized Ginkgo biloba extract (Ecb 761) in the management of congestive symptoms of premenstrual syndrome]" (article in French). Revue françoise de gynécologie et d'obstétrique Vol. 88, No. 7–9 (1995): 447–457.
- (1993): 44/-45/.
  (1993): 44/-45/.
  Schellenberg, R., et al. "Dose-dependent efficacy of the Vitex agnus castus extract Ze 440 in patients suffering from premenstrual syndrome." *Phytomedicine* Vol. 19, No. 14 (2012): 1325–1331.
  4. Ma, L., et al. "Treatment of moderate to severe premenstrual syndrome with Vitex agnus castus (BNO 1095) in Chinese women." *Gynecological Endocrinology* Vol. 26, No. 8 (2010): 612–616.
  5. van Die, M.D., et al. "Vitex agnus-castus extracts for female reproductive disorders: A systematic review of clinical trials."
- Van Die, M.D., et al. "Vitex agnus-casus extracts for temate reproductive disorders: A systematic review of culnical traits." *Planta Medica* Vol. 79, No. 7 (2013): 562–572.
   Allahtavakoli, M., et al. "Vitex agnus castus extracts improves learning and memory and increases the transcription of estrogen receptor in hipporcampus of ovariatedomized ratis." *Basic and Clinical Neuroscience* Vol. 6, No. 3 (2015): 163–5742.
   Sharma, P., et al. "Role of bromocriptine and pyridoxine in premenstrual tension syndrome." *Indian Journal of Physiology and Pharmacology* Vol. 51, No. 4 (2007): 368–374.
   Statizadeh, N., et al. "Evaluating the effect of magnesium and magnesium plus vitamin B, supplement on the severity of premenstrual syndrome." *Iranian Journal of Nursing and Midwifery Research* Vol. 15, Suppl. 1 (2010): 401–405.