

SomnoPress®

Synergy of sleep-regulating and calming effects of melatonin and L-theanine

For Professional Use
(in integrative oncology or other areas of practice)

Vitazan Professional's SomnoPress® is a fast-acting, chewable supplement to encourage a calm and restorative sleep, especially for nighttime waking. **Each chewable tablet contains 125 mg of L-theanine and 0.5 mg of melatonin**, allowing for an easy dosing or combining with additional melatonin, such as high-dose melatonin. SomnoPress® is **sugarless** and grape-flavoured.

L-Theanine

L-Theanine, as shown in a systematic review, may assist in the reduction of stress and anxiety in people exposed to stressful conditions.¹ L-Theanine has also been investigated as an agent to **promote good quality of sleep through anxiolysis without causing drowsiness or sedation**.² This anxiolytic effect may be mediated through the **induction of alpha brain waves**³ and through the **inhibition of cortical neuron excitation**.⁴

In a randomized, placebo-controlled, crossover, and double-blind trial, the effect of L-theanine on stress-related symptoms and cognitive function was investigated in 30 healthy subjects. Administration of 200 mg/d of L-theanine for four weeks compared to placebo had a significant beneficial effect on the Pittsburgh Sleep Quality Index scores ($p = 0.013$), Self-rating Depression Scale ($p = 0.019$), and State-Trait Anxiety Inventory ($p = 0.006$). The Pittsburgh Sleep Quality Index subscale scores for sleep latency, sleep disturbance, and use of sleep medication reduced in the treatment group compared to the placebo group (all $p < 0.05$).⁵

An open-label clinical trial on the effectiveness of L-theanine in 20 patients with major depressive disorder resulted in beneficial effects on depressive symptoms, anxiety, sleep disturbance, and cognitive

impairments. The 8-week trial of 250 mg/d of L-theanine resulted in a significant reduction in Hamilton Depression Rating Scale ($p = 0.004$), State-Trait Anxiety Inventory ($p = 0.012$), and Pittsburgh Sleep Quality Index ($p = 0.030$); and cognitive function improved with decreased response latency ($p = 0.001$) and error rate ($p = 0.036$) in the Stroop test, and enhanced verbal memory ($p = 0.005$) and executive function ($p = 0.016$) in the Brief Assessment of Cognition in Schizophrenia.⁶

Melatonin

Exogenous melatonin for primary and secondary sleep disorders reduces sleep-onset latency and increases total sleep time.^{7,8} Furthermore, melatonin has been investigated in the context of cancer care.^{9,10,11,12,13,14} A systematic review investigating the effect of melatonin on sleep quality and insomnia in patients with cancer concluded that 3–20 mg of melatonin used for 10 days to 4 months may be effective in improving sleep quality and insomnia.¹⁵

In a 14-day placebo-controlled, double-blind, randomized trial, melatonin was studied in 50 patients with malignancies suffering from insomnia. The melatonin group showed clinically relevant improvements in insomnia (46.53%; $p = 0.00001$ v. 11.30%; $p = 0.1026$). The improvement in sleep from day 1 to day 7 were significant (19.91%; $p = 0.00001$ v. 0.98%; $p = 0.2563$), and greater significant improvements were seen between 7 and 14 days (33.24%; $p = 0.00001$ v. 10.42%; $p = 0.1469$) compared to the control group. The authors concluded that daily



The first company in the industry to have invested in an ISO 17025-accredited laboratory to test for identity, potency, oxidation, disintegration, purity, and more.



3405, F.-X.-Tessier street, Vaudreuil-Dorion (Québec), J7V 5V5 · 1 888 863 9274 · vitazan.com · info@vitazan.com



intake of melatonin 2 hours before bedtime improved sleep induction and quality in cancer patients with insomnia.¹⁶

In a double-blind, placebo-controlled, randomized trial involving 48 participants, the use of 6 mg/d of melatonin before bedtime in the perioperative period after breast-cancer surgery was investigated. Patients in the melatonin group received melatonin before bedtime 3 nights preoperatively, and continued until at least 1 week postoperatively. Melatonin use significantly changed sleep efficiency and wake after sleep onset after surgery.¹⁷

In a single-blind trial, 90 colorectal-cancer patients undergoing chemotherapy were randomized to receive either 6 mg of melatonin at bedtime or 10 mg of zolpidem (a short-term nonbenzodiazepine treatment for insomnia). Both melatonin and zolpidem had significant impacts on sleep quality in week 4 ($p < 0.05$). Both treatments were found to improve sleep disturbances by affecting the sleep parameters including sleep quality, sleep duration, sleep latency, sleep disorders, need for sleeping medicines, sleep efficiency, daytime dysfunction, and high-altitude sleep overnight.¹⁸

Each chewable tablet contains:

L-Theanine 125 mg
Melatonin (N-acetyl-5-methoxytryptamine) 500 mcg

Nonmedicinal ingredients: Natural grape flavour, mannitol, xylitol, vegetable stearic acid, DL-malic acid, dicalcium phosphate, and vegetable magnesium stearate.

Directions of use: Adults: Take 2 tablets daily or as directed by your health-care practitioner. **Jet lag:** Take once a day at bedtime, while travelling, and at destination until adapted to the new time zone/or daily pattern. **All other uses:** Take once a day, at or before bedtime.

Duration of use: Consult a health-care practitioner for use beyond 4 weeks.

Cautions and warnings: Avoid taking with alcohol or products that cause drowsiness. Consult a health-care practitioner if sleeplessness persists for more than 4 weeks (chronic insomnia). Consult a health-care practitioner prior to use if you are taking medications for seizure, blood pressure, to suppress the immune system (immunosuppressive medications), to affect mental state or increase sedation, steroids, or blood thinners; or if you have cardiovascular, immune, liver, or chronic kidney disease, hormonal or seizure disorders, asthma, depression, diabetes, low blood sugar, or migraine.

Contraindications: Do not drive or use machinery for 5 hours after taking melatonin. Do not use this product if you are pregnant or breast-feeding.

Known adverse reactions: Discontinue use if allergy occurs or if you experience headache, confusion, or nausea.

Product #2723 · 60 chewable tablets · NPN 80112125

References

- Williams, J.L., J.M. Everett, N.M. D'Cunha, D. Sergi, E.N. Georgousopoulou, R.J. Keegan, A.J. McKune, D.D. Mellor, N. Anstice, and N. Naumovski. "The effects of green tea amino acid L-theanine consumption on the ability to manage stress and anxiety levels: A systematic review." *Plant Foods for Human Nutrition*, Vol. 75, No. 1 (2020): 12–23.
- Rao, T.P., M. Ozeki, and L.R. Juneja. "In search of a safe natural sleep aid." *Journal of the American College of Nutrition*, Vol. 34, No. 5 (2015): 436–447.
- Rao, Ozeki, and Juneja. "In search of a safe natural sleep aid."
- Kimura, K., M. Ozeki, L.R. Juneja, and H. Ohira. "L-Theanine reduces psychological and physiological stress responses." *Biological Psychology*, Vol. 74, No. 1 (2007): 39–45.
- Hideese, S., S. Ogawa, M. Ota, I. Ishida, Z. Yasukawa, M. Ozeki, and H. Kunugi. "Effects of L-theanine administration on stress-related symptoms and cognitive functions in healthy adults: A randomized controlled trial." *Nutrients*, Vol. 11, No. 10 (2019): 2362.
- Hideese, S., M. Ota, C. Wakabayashi, T. Noda, H. Ozawa, T. Okubo, and H. Kunugi. "Effects of chronic L-theanine administration in patients with major depressive disorder: An open-label study." *Acta Neuropsychiatrica*, Vol. 29, No. 2 (2017): 72–79.
- Auld, F., E.L. Maschauer, I. Morrison, D.J. Skene, and R.L. Riha. "Evidence for the efficacy of melatonin in the treatment of primary adult sleep disorders." *Sleep Medicine Reviews*, Vol. 34 (2017): 10–22.
- Li, T., S. Jiang, M. Han, Z. Yang, J. Lv, C. Deng, R.J. Reiter, and Y. Yang. "Exogenous melatonin as a treatment for secondary sleep disorders: A systematic review and meta-analysis." *Frontiers in Neuroendocrinology*, Vol. 52 (2019): 22–28.
- Auld, F., E.L. Maschauer, I. Morrison, D.J. Skene, and R.L. Riha. "Evidence for the efficacy of melatonin in the treatment of primary adult sleep disorders." *Sleep Medicine Reviews*, Vol. 34 (2017): 10–22.
- Li et al. "Exogenous melatonin as a treatment for secondary sleep disorders."
- Talib, W.H., A.R. Alsayed, A. Abuawad, S. Daoud, and A.M. Mahmod. "Melatonin in cancer treatment: Current knowledge and future opportunities." *Molecules*, Vol. 26, No. 9 (2021): 2506.
- Souza Palmer, A.C., M. Zortea, A. Souza, V. Santos, J. Villanova Biazios, I.L.S. Torres, F. Fregni, and W. Caumo. "Clinical impact of melatonin on breast cancer patients undergoing chemotherapy; effects on cognition, sleep and depressive symptoms: A randomized, double-blind, placebo-controlled trial." *PLoS One*, Vol. 15, No. 4 (2020): e0231379.
- Innominato, P.F., A.S. Lim, O. Palesh, M. Clemons, M. Trudeau, A. Eisen, C. Wang, A. Kiss, K.I. Pritchard, and G.A. Bjarnason. "The effect of melatonin on sleep and quality of life in patients with advanced breast cancer." *Support Care in Cancer*, Vol. 24, No. 3 (2016): 1097–1105.
- Chen, W.Y., A. Giobbie-Hurder, K. Gantman, J. Savoie, R. Scheib, L.M. Parker, and E.S. Scherhammer. "A randomized, placebo-controlled trial of melatonin on breast cancer survivors: Impact on sleep, mood, and hot flashes." *Breast Cancer Research and Treatment*, Vol. 145, No. 2 (2014): 381–388.
- Jafari-Koulaee, A., and M. Bagheri-Nesami. "The effect of melatonin on sleep quality and insomnia in patients with cancer: A systematic review study." *Sleep Medicine*, Vol. 82 (2021): 96–103.
- Kurdi, M.S., and S.P. Muthukalai. "The efficacy of oral melatonin in improving sleep in cancer patients with insomnia: A randomized double-blind placebo-controlled study." *Indian Journal of Palliative Care*, Vol. 22, No. 3 (2016): 295–300.
- Madsen, M.T., M.V. Hansen, L.T. Andersen, I. Hageman, L.S. Rasmussen, S. Bokmand, J. Rosenberg, and I. Gögenur. "Effect of melatonin on sleep in the perioperative period after breast cancer surgery: A randomized, double-blind, placebo-controlled trial." *Journal of Clinical Sleep Medicine*, Vol. 12, No. 2 (2016): 225–233.
- Shahrokhi, M., P. Ghaeli, P. Arya, A. Shakiba, A. Noormandi, M. Soleimani, and M. Esfandbod. "Comparing the effects of melatonin and zolpidem on sleep quality, depression, and anxiety in patients with colorectal cancer undergoing chemotherapy." *Basic and Clinical Neuroscience*, Vol. 12, No. 1 (2021): 105–114.

SomnoPress® NDMAPS™ Data Collection

Key Benefits from the Case Series

- Improved sleep onset
- Decreased feelings of morning grogginess
- Less effect on sleep cycles
- Easy to use, before bed or upon waking in the night

Featured Benefits in Cases with SomnoPress®

Chief Concern	Benefits
Insomnia with breast cancer	Works really well
Insomnia with hypothyroidism	Sleep onset and quality much improved
Type 2 diabetes	Longer sleep time, nocturnal waking
Insomnia with multiple myeloma	Helpful to fall back to sleep on waking
Insomnia with breast cancer	Helps with zopiclone

Number of Cases with Benefits from SomnoPress®

Total number of cases: 21

