

N.B. TO GIVE IT TO YOUR PHARMACIST OR DOCTOR

VITOLI SLEEP - PRECAUTIONS

Side effects

The various ingredients in the Vitoli SLEEP product have little specific or serious toxicity. However, some users have reported some side effects such as drowsiness, headache, dizziness, depressive symptoms, decreased alertness, excitement, irritability, discomfort, or mild gastrointestinal upset. However, the clinical information we currently have, shows that the Vitoli SLEEP product has undeniable efficacy with a reassuring profile of side effects.

It is always possible that a hypersensitivity (ex: allergy) to one of the ingredients of the preparation could manifest itself. In such a case, it is recommended to stop using it and consult a health professional if serious allergy symptoms persist.

Contraindications

Given the possible drowsiness, driving a car or any other activity requiring great concentration should be avoided, especially within 4 to 6 hours of taking it. Melatonin may be contraindicated in the presence of depression, diabetes, liver problems and epilepsy, and with NIFEDIPINE (= ADALAT trade name) (decreased effect of NIFEDIPINE). However, we believe that cases of depression and diabetes should constitute surveillance (and not strict contraindications) for which improved sleep could be of great benefit.

Interactions

Theoretically, the Vitoli SLEEP product could increase the sedative effect of alcohol, barbiturates, benzodiazepines, any other tranquilizer, hypnotic or sedative, or even certain other natural products such as kava, chamomile, lemon balm, etc...

Because of the presence of melatonin, the Vitoli SLEEP product may decrease the effectiveness of certain hypertension medications. However, it is also known that improving sleep and reducing stress and anxiety helps lower blood pressure (when monitored). It is also recommended to avoid it during immunosuppressive therapy (melatonin could affect immune function).

Fluvoxamine and Melatonin: by inhibiting CYP1A2 fluvoxamine could significantly increase the plasma concentrations of Melatonin, thus increasing the possible side effects. It is best to avoid this product for this case, due to the potential excessive sleepiness in the patient.

Quality olive extracts could lower blood pressure, improve glucose management, and reduce blood clotting. However, the dose used is the average food dose consumed in the Mediterranean diet and it is not linked to any significant interaction effect. Health Canada has not reported this risk as significant.

www.vitoli.ca - professionnels@vitoli.ca

(438) 794-3372

Pregnancy and breast feeding

There is no safety data available for certain ingredients or certain contraindications being reported for the other ingredients. **It is therefore contraindicated to use it during pregnancy and not recommended to use it if you are breastfeeding.**

Caution

The content of medicinal plants naturally varies according to the production site or according to the extraction conditions. Therefore, there are many variations in the composition of ingredients available from one brand of product to another. It is strongly recommended to use quality products, these being standardized to contain sufficient quantities of active substances for each plant, which ensures their effectiveness, confirms the origin of the plant and its safety. Canadian regulations do not require companies to meet these standards; the majority of plant extracts on the market are not standardized. The information in this document only applies to products in the Vitoli product line.

According to Health Canada (2016), the use of melatonin in children and adolescents should be treated with caution, although it is actually used occasionally according to current data. This should only be done on the recommendation of a healthcare practitioner.

André Perreault, pharmacist,
Professional services
Idunn Technologies

Revised by Jean-Yves Dionne,
Apothecary Academy (www.apothicaire.ca)

References:

- 1.Natural Medicines Comprehensive Database, Therapeutic Research Faculty, 2010**
- 2.Passeportsanté.net.Valériane. www.passeportsante.net**
- 3.The Review of Natural Products, 6 ième édition, 2010**
- 4.Barnes J. Et Al. Herbal Medicines, 2 ième edition, Pharmaceutical Press, 2002**
- 5.Santé Canada, Base de donnée des produits de santé naturels**
- 6.Facts and Comparisons, The Lawrence review of natural products, 1998**
- 7.Herbal Companion to AHFS DI, American Society of Health-System Pharmacist, 2001**