

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

To be allocated.

PROPRIETARY NAME AND DOSAGE FORM:

Deep Sleep™ (capsules).

COMPOSITION (per capsule):

Ingredients:	
Griffonia simplicifolia (5HTP)	50mg
Passiflora incarnate (Passionflower)	750mg
Eschscholtzia californica (Californian Poppy)	200mg
Piscidia piscipula (Jamaican Dogwood)	50mg
Vitamins & Minerals	
Magnesium Oxide (Equivalent Magnesium 30mg)	50mg
Pyridoxine Hydrochloride (Vitamin B6)	1mg
Encapsulating Aids:	
Magnesium Stearate, Microcrystalline Cellulose.	

This product is not suitable for vegans and vegetarians. (Contains Sugar)

PHARMACOLOGICAL CLASSIFICATION:

Category D (Complementary Medicine) – Combination Product.
This medicine has not been evaluated by SAHPRA for its quality, safety and intended use.

PHARMACOLOGICAL ACTION

PHARMACOKINETICS:

Deep Sleep™ is a combination of Griffonia simplicifolia (5HTP), Passiflora incarnata (Passion flower), Eschscholtzia californica (Californian poppy), Piscidia piscipula (Jamaican dogwood), Magnesium and Pyridoxine on which pharmacokinetic studies have not been conducted.

PHARMACODYNAMICS:

Deep Sleep™ is a combination product which is beneficial for individuals who required assistance for relaxation, insomnia, anxiety and tension.

Griffonia simplicifolia (5HTP - Serotonin) is involved in the central nervous system regulation of mood, appetite and sleep.

Passion Flower provides nervous system support which is beneficial for stress, tension and nervousness. It may also be beneficial in inducing sleep to provide a better quality of sleep.

California Poppy promotes a healthy sleeping pattern by maintaining consistent sleep throughout the night. It may also soothe stress, relax muscles and provide overall relaxation.

Jamaican Dogwood has sedative, anti-spasmodic and anti-inflammatory activity. It may be beneficial for insomnia, nervous tension and headaches.

Magnesium aids the relaxation of muscles thereby having an overall calming and relaxing effect.

Pyridoxine Hydrochloride is required for the absorption and activities of Magnesium by ensuring normal cellular levels are maintained.

INDICATIONS:

Deep Sleep™ is a herbal, vitamin and mineral combination product which assists individuals who require nervous system support to help them with relaxation, insomnia, anxiety and tension.

CONTRAINDICATIONS:

This product is not suitable for individuals under the age of 16 years. Do not use if a known hypersensitivity or allergy exists towards any of the ingredients. If in doubt, consult your medical practitioner.

It should not be taken by individuals who are on any sedative, antiparkinson or antidepressant medication (in particular; Selective Serotonin Reuptake Inhibitors) as it may result in Serotonin Syndrome.

WARNINGS AND SPECIAL PRECAUTIONS:

Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or healthcare professional for advice. Complementary medicines may take longer to have the desired therapeutic effect as it works by regulating the natural sleep-wake cycle. Do not exceed the recommended daily dosage of 3 capsules. Do not use after the expiry date.

Deep Sleep™ may affect an individual's ability to drive or operate machinery.

INTERACTIONS:

If you are taking any chronic medication, do not use this product without consulting your medical practitioner.

Antiparkinson/Antidepressant/Sedative (Selective Serotonin Reuptake Inhibitors) – Concomitant use with **Deep Sleep™** may result in Serotonin Syndrome.

PREGNANCY AND BREASTFEEDING:

Do not use this product if you are pregnant or breastfeeding as safety has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Always tell your healthcare professional if you are taking any other medicine.

Acute Insomnia: 1-3 capsules with water, 60-90 minutes before retiring unless otherwise prescribed.

Chronic Insomnia: 3 capsules with water at night for at least two weeks.

Anxiety: May be taken throughout the day. Do not exceed the recommended daily dosage of 3 capsules.

SIDE EFFECTS:**Immune System Disorders:**

Frequency unknown: Hypersensitivity reactions

Nervous System Disorders:

Frequency unknown: Serotonin syndrome

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

In the event of overdosage, consult your healthcare professional or pharmacist. If neither is available, contact your nearest hospital or poison centre. Treatment is symptomatic and supportive.

IDENTIFICATION:

A light brown powder in a clear hard gelatine capsule.

PRESENTATION:

30 capsules in a white bottle with an induction seal and tamper proof lid.

STORAGE INSTRUCTIONS:

Store below 30°C in a dry place.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF APPLICANT:

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DATE OF REGISTRATION

To be confirmed

CATEGORY

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Good Health Products Pty Ltd

REFERENCES

1. Caruso I, Puttini PS (1992) 'Primary fibromyalgia syndrome and 5-hydroxy-L-tryptophan 90-day open study' Journal of Internal Medical Research
2. Cangiano C, et al., (1992) 'Eating behaviour and adherence to dietary prescriptions in obese adult subjects treated with 5-hydroxytryptophan' American Journal of Clinical Nutrition
3. De Benedittis G et al., (1986) '5-HT precursors in migraine prophylaxis: A double blind cross-over study with L-5 hydroxytryptophan versus placebo' Clinical Journal of Pain
4. Akhondzadeh S et al., (2001) 'Passionflower in the treatment of generalised anxiety: a pilot double-blind randomized controlled trial with oxazepam' Journal of Clinical Pharmaceutical Therapy
5. Murray, MT & Pizzorno, JE (1999) Textbook of Natural Medicine 2nd Edition, Harcourt Publishers Ltd UK, page 784 & 1354
6. Nakajima T et al., (1978) 'Clinical evaluation of 5-hydroxy-L-tryptophan as an antidepressant drug' Folia Psychiatrica Neurologica Japonica