

Afrasia Health Sleep Support

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

Afrasia Health Sleep Support capsules

COMPOSITION

Each capsule contains:

Ocimum tenuiflorum (Holy Basil) (leaf extract)	250 mg
Valeriana wallichii (Valerian)	100 mg
Magnesium glycinate	50 mg
providing Magnesium (elemental)	5,85 mg

Other excipients: Magnesium stearate, potato starch, silicon dioxide.

Capsules are free of gluten, sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION

Category D Complementary Medicine

33.7 Combination Product

PHARMACOLOGICAL ACTION

Valerian is a herbal medicinal product for relief of mild nervous tension and to aid sleep.

Holy Basil is a traditional medicinal herb, which acts on the central nervous system to bring about a mild anxiolytic action. Magnesium glycinate has a calming effect on the brain due to the presence of glycine, which helps relieve anxiety and promote better sleep.

INDICATIONS

Afrasia Health Sleep Support is used as a supportive aid for insomnia or sleep disturbances, in the absence of clinical anxiety or depression.

CONTRAINDICATIONS

Hypersensitivity (allergy) to any of the ingredients in the formulation. There are no known contraindications when used at the recommended dose.

WARNINGS AND SPECIAL PRECAUTIONS

If your general health worsens while taking Afrasia Health Sleep Support, please consult your healthcare provider.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

INTERACTIONS

There are no known interactions.

PREGNANCY AND LACTATION

The safety and efficacy of Afrasia Health Sleep Support capsules during pregnancy and lactation have not been established. This medicine should therefore not be taken during pregnancy and lactation.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

It is unlikely that Afrasia Health Sleep Support capsules will affect the ability to drive or operate machines.

DOSAGE AND DIRECTIONS FOR USE

As a dietary supplement for adults, take two capsules with water 1 hour before bedtime, after food, or as directed by your healthcare provider.

To achieve an optimal effect, use over 2-4 weeks is recommended. If the symptoms persist or worsen after 2 weeks of continued use, consult your healthcare provider.

SIDE EFFECTS

Valerian: Side effects may include headache and gastrointestinal disturbances such as nausea, abdominal cramps and diarrhoea.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment is symptomatic and supportive.

IDENTIFICATION

White vegcap.

PRESENTATION

Pack size of 60 white capsules in a white plastic bottle, in a carton. Pack size of 20 white capsules, made up of 2 x blister strips each with 10 capsules per blister enclosed in a cardboard carton.

STORAGE INSTRUCTIONS

Store in a cool dry place (at or below 25°C) and keep away from direct light. Keep the container tightly closed.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

NAME AND BUSINESS ADDRESS OF THE APPLICANT

Grischo (Pty) Ltd
Unit A, 3 Williams Road, Bedfordview, 2007

CUSTOMER CARE

info@afrasiahealth.co.za

DATE OF PUBLICATION OF THIS PACKAGE INSERT

TBA

SLP-PI-02