Afrasia Health Sleep Support

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
Unscheduled

Afrasia Health Sleep Support capsules
Ocimum tenuiflorum (Holy Basil)
Valeriana wallichii (Valerian)
Magnesium glycinate
Passiflora incarnata (Passion flower)
Sugar free

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

Read all of this leaflet carefully because it contains important information for you.
Afrasia Health Sleep Support is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Afrasia Health Sleep Support carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What Afrasia Health Sleep Support is and what it is used for
2. What you need to know before you take Afrasia Health Sleep Support
3. How to take Afrasia Health Sleep Support
4. Possible side effects
5. How to store Afrasia Health Sleep Support
6. Contents of the pack and other information

1. What Afrasia Health Sleep Support is and what it is used for
Afrasia Health Sleep Support is a traditional use, combination supplement and is used as a supportive aid for insomnia or sleep disturbances, in the absence of clinical anxiety or depression.

2. What you need to know before you take Afrasia Health Sleep Support
Do not take Afrasia Health Sleep Support:

- if you are hypersensitive (allergic) to any of the ingredients of Afrasia Health Sleep Support (listed in section 6).

There are no known contraindications when Afrasia Health Sleep Support is used at the recommended dose.

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

Other medicines and Afrasia Health Sleep Support
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Concomitant use of this medicine with medication that has sedative properties may cause additive effects and side effects.

Afrasia Health Sleep Support with food and drink
See section 3 **(How to take Afrasia Health Sleep Support).**

Pregnancy, breastfeeding and fertility
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.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines
Avoid operation of machinery or driving when taking Afrasia Health Sleep Support, as the use of this medicine is as a sleep aid, and will cause drowsiness.
It is not always possible to predict to what extent Afrasia Health Sleep Support may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Afrasia Health Sleep Support affects them.

3. How to take Afrasia Health Sleep Support
Do not share your medicines with any other person.
Always take Afrasia Health Sleep Support exactly as described in this leaflet, or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is:
Adults: Take 1-2 capsules with water 1 hour before bedtime, after food, or as directed by your healthcare provider.

It is recommended that you use Afrasia Health Sleep Support over 2-4 weeks to achieve an optimal effect.

If the symptoms persist or worsen after 2 weeks of continued use, let your healthcare provider know.

If you take more Afrasia Health Sleep Support that you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Afrasia Health Sleep Support
Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects
Afrasia Health Sleep Support can have side effects.
Common side effects may include dizziness and confusion.
Less frequent side effects may include headache and gastrointestinal disturbances such as nausea, stomach cramps and diarrhoea.

Not all side effects reported for Afrasia Health Sleep Support are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Afrasia Health Sleep Support, please consult your healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist.
You can report side effects to info@afrasiahealth.co.za
You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 .
By reporting side effects, you can help provide more information on the safety of Afrasia Health Sleep Support.

5. How to store Afrasia Health Sleep Support
- Store all medicines out of reach of children.
- Store in a cool dry place, at or below 25ºC, and keep away from direct light.
- Store in the original container
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What Afrasia Health Sleep Support contains
Each capsule contains the following active ingredients:

Ocimum tenuiflorum (Holy Basil) *(herb powder)*	250 mg
Valeriana wallichii (Valerian) *(root 10:1 extract)*	150 mg
Magnesium glycinate	50 mg
providing Magnesium (elemental)	5,85 mg
Passiflora incarnata (Passion flower) *(herb 4:1 extract)*	45 mg

The other ingredients are magnesium stearate, silicon dioxide.
The capsules are free of gluten, sugar and lactose.

What Afrasia Health Sleep Support looks like and contents of the pack
Pack size of 60 white capsules in a 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.

Holder of Certificate of Registration
Grischo (Pty) Ltd
Unit A, 3 Williams Road, Bedfordview, 2007
info@afrasiahealth.co.za

This leaflet was last revised in
October 2024

Registration number
Will be allocated by the SAHPRA upon registration

Access to the corresponding Professional Information
The Professional information leaflet is available at:
https://www.afrasiahealth.co.za/

SLP-PIL-04

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS
Ongeskeduleer

Afrasia Health Sleep Support kapsules
Ocimum tenuiflorum (Holy Basil)
Valeriana wallichii (Valeriaan)
Magnesiumglikinaat
Passiflora incarnata (Passieblom)
Suikervry

KOMPLEMENTÊRE MEDISYNE:
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.
Afrasia Health Sleep Support is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy Afrasia Health Sleep Support versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad
1. Wat Afrasia Health Sleep Support is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy Afrasia Health Sleep Support neem
3. Hoe om Afrasia Health Sleep Support te neem
4. Moontlike newe-effekte
5. Hoe om Afrasia Health Sleep Support te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat Afrasia Health Sleep Support is en waarvoor dit gebruik word
Afrasia Health Sleep Support is 'n tradisionele-gebruik, kombinasie-aanvulling, en word gebruik as 'n ondersteunende hulpmiddel vir slapeloosheid of slaapstoornisse, in die afwesigheid van kliniese angs of depressie.

2 Wat jy moet weet voordat jy Afrasia Health Sleep Support neem
Moet nie Afrasia Health Sleep Support neem:

- indien jy hipersensitief (allergies) is vir enige van die bestanddele van Afrasia Health Sleep Support (sien **Wat Afrasia Health Sleep Support bevat**)

Daar is geen bekende kontraindikasies as Afrasia Health Sleep Support teen die aanbevole dosis gebruik word nie.

Waaskuwings en voorsorgmaatreëls
Indien jou algemene gesondheid verswak gedurende die gebruik van Afrasia Health Sleep Support, raadpleeg jou gesondheidsorgverskaffer.

Ander medisyne en Afrasia Health Sleep Support
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.) Gelyktydige gebruik van hierdie medisyne met medikasie wat sederende eienskappe bevat, mag die effek daarvan vererger en newe-effekte veroorsaak.

Afrasia Health Sleep Support met voedsel en drank
Sien afdeling 3 **(Hoe om Afrasia Health Sleep Support te neem).**

Swangerskap, borsvoeding en vrugbaarheid
Die veiligheid en effektiwiteit van Afrasia Health Sleep Support kapsules tydens swangerskap en borsvoeding is nie vasgestel nie. Hierdie medisyne moet tydens swangerskap en borsvoeding nie geneem word nie. Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy die medisyne neem.

Bestuur en die gebruik van masjiene
Vermy die gebruik van masjinerie of bestuur wanneer jy Afrasia Health Sleep Support neem, aangesien die gebruik van hierdie medisyne as 'n slaaphulpmiddel is, en lomerigheid sal veroorsaak.

Dit is nie altyd moontlik om te voorspel in watter mate Afrasia Health Sleep Support die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet toesien dat hulle nie aan bogenoemde aktiwiteite deelneem nie, totdat hulle bewus is van die uitwerking wat Afrasia Health Sleep Support op hulle sal hê.

3. Hoe om Afrasia Health Sleep Support te neem
Moet nie jou medisyne met enige ander persoon deel nie.
Neem Afrasia Health Sleep Support altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus jou dokter of apteker indien jy onseker is.
Die gewone dosis is:
Volwassenes Neem 1-2 kapsules met water een uur voor slaaptyd, na ete, of soos voorgeskryf deur jou gesondheidsorgverskaffer.

Dit word aanbeveel dat jy Afrasia Health Sleep Support vir 2-4 weke gebruik om 'n optimale effek te kry.
As die simptome voortduur of vererger na 2 weke van voortgesette gebruik, vertel vir jou gesondheidsorgverskaffer.

As jy meer Afrasia Health Sleep Support neem as wat jy moet
In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om Afrasia Health Sleep Support te neem
Moet nie 'n dubbele dosis neem om vir die vergete dosis op te maak nie.

4. Moontlike newe-effekte
Afrasia Health Sleep Support kan newe- effekte hê.
Algemene newe-effekte kan duiseligheid en verwarring unsluit.
Minder gereelde newe-effekte kan hoofpyn en gastro-intestinale versteurings soos naarheid, maagkrampe en diarree insluit.

Nie alle newe-effekte wat vir Afrasia Health Sleep Support gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte onderwind terwyl jy Afrasia Health Sleep Support neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan newe-effekte by info@afrasiahealth.co.za rapporteer. Jy kan ook newe-effekte aan SAHPRA rapporteer deur die **"6.04 Adverse Drug Reaction Reporting Form"** te gebruik, aanlyn gevind onder SAHPRA se publikasies:
https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte te rappoeteer kan jy help om meer inligting rakende die veiligheid van Afrasia Health Sleep Support te verskaf.

5. Hoe om Afrasia Health Sleep Support te bêre
- Bêre alle medisyne buite die bereik van kinders.
- Bêre in 'n koel droë plek, teen of benede 25°C, en hou weg van direkte lig.
- Bewaar in die oorspronklike houer.
- Moet nie gebruik word na die vervaldatum wat op die houer gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting
Wat Afrasia Health Sleep Support bevat
Elke kapsule bevat die volgende aktiewe bestanddele:

Ocimum tenuiflorum (Holy Basil) *(kruie poeier)*	250 mg
Valeriana wallichii (Valeriaan) *(wortel 10:1 uittreksel)*	150 mg
Magnesiumglikinaat	50 mg
verskaf Magnesium (elementér)	5,85 mg
Passiflora incarnata (Passieblom) *(kruie 4:1 uittreksel)*	45 mg

Die ander bestanddele is magnesiumstearaat, silikondioksied.
Die kapsules bevat geen gluten, suiker en laktose.

Hoe Afrasia Health Sleep Support lyk en die inhoud van die verpakking
Pakgrootte van 60 wit kapsules in 'n wit plastiekbottel, in 'n karton.
Pakgrootte van 20 wit kapsules, bestaan uit 2 x blisterstroke elk met 10 kapsules per blister wat binne-in 'n kartonhouer is.

Houer van Registrasiesertifikaat
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Hierdie inligtingsblad is hersien in
Oktober 2024

Toegang tot die ooreenstemmende professionele inligting
Die Professionele inligtingsblad is beskikbaar by:
https://www.afrasiahealth.co.za/