

SCHEDULING STATUS

Unscheduled

Afrasia Health Stress Support capsules

Withania somnifera (Ashwagandha)
Ocimum tenuiflorum (Holy Basil)
Bacopa monnieri (Bacopa/Brahmi)

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 Stress Support is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Afrasia Health Stress 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

- What Afrasia Health Stress Support is and what it is used for
- What you need to know before you take Afrasia Health Stress Support
- How to take Afrasia Health Stress Support
- Possible side effects
- How to store Afrasia Health Stress Support
- Contents of the pack and other information

1. What Afrasia Health Stress Support is and what it is used for
Afrasia Health Stress Support is a traditional use herbal supplement, and is used to assist in relief of occasional stress.

2. What you need to know before you take Afrasia Health Stress Support

Do not take Afrasia Health Stress Support:

- if you are hypersensitive (allergic) to any of the ingredients of Afrasia Health Stress Support (listed in section 6).
- if you are taking medication that suppresses or reduces the strength of your body's immune system.

Warnings and precautions

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

Other medicines and Afrasia Health Stress Support

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) Please consult your healthcare provider before taking Afrasia Health Stress Support if you are currently taking barbiturates (medication that acts as a central nervous system depressant), as the combination may increase the sedative effect.

Afrasia Health Stress Support with food and drink

See section 3 (How to take Afrasia Health Stress Support).

Pregnancy, breastfeeding and fertility

The safety and efficacy of Afrasia Health Stress 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

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

It is not always possible to predict to what extent Afrasia Health Stress 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 Stress Support affects them.

3. How to take Afrasia Health Stress Support

Do not share your medicines with any other person.

Always take Afrasia Health Stress 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 capsule twice daily with water before meals, or as directed by your healthcare provider.

If you take more Afrasia Health Stress 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 Stress Support

Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

Afrasia Health Stress Support can have side effects.

Ashwagandha: Frequent side effects include mild to moderate drowsiness that lasts for a short time, upper gastrointestinal discomfort (which may present as upper abdominal pain, indigestion, or bloating), and diarrhoea.

Bacopa: Frequent side effects may include flu-like symptoms, gastrointestinal irritation, nausea, dry mouth, increased bowel movements and muscle weakness or pain.

Not all side effects reported for Afrasia Health Stress Support are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Afrasia Health Stress 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 also report side effects to info@grischo.co.za

By reporting side effects, you can help provide more information on the safety of Afrasia Health Stress Support.

5. How to store Afrasia Health Stress Support

- Store all medicines out of reach of children.
- Store in a cool dry place, at or below 25°C, and keep away from direct light.
- Keep the container tightly closed.
- 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 Stress Support contains

Each capsule contains the following active ingredients:

Withania somnifera (Ashwagandha)	250 mg
Ocimum tenuiflorum (Holy Basil) (leaf extract)	50 mg
Bacopa monnieri (Bacopa/Brahmi) (10% bacoside)	50 mg

The other ingredients are microcrystalline cellulose, silicon dioxide, magnesium stearate.

The capsules are free of gluten, sugar and lactose.

What Afrasia Health Stress Support looks like and contents of the pack

A white plastic bottle with a screw cap, pressure seal, packed in a carton.

Each bottle contains 60 white capsules.

Holder of Certificate of Registration

Grischo (Pty) Ltd
Unit 2B 80A Concorde Road East, Bedfordview, 2007
info@grischo.co.za

This leaflet was last revised in

Will be allocated by the SAHPRA upon registration.

Registration number

Will be allocated by the SAHPRA upon registration

SKEDULERINGSTATUS

Ongeskeduleer

Afrasia Health Stress Support kapsules

Withania somnifera (Ashwagandha)
Ocimum tenuiflorum (Holy Basil)
Bacopa monnieri (Bacopa/Brahmi)

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 Stress Support is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy Afrasia Health Stress 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

- Wat Afrasia Health Stress Support is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy Afrasia Health Stress Support neem
- Hoe om Afrasia Health Stress Support te neem
- Moontlike newe-effekte
- Hoe om Afrasia Health Stress Support te bêre
- Inhoud van die verpakking en ander inligting

1. Wat Afrasia Health Stress Support is en waarvoor dit gebruik word

Afrasia Health Stress Support is 'n tradisionele kruie-aanvulling en word gebruik om af en toe stres te verlig.

2. Wat jy moet weet voordat jy Afrasia Health Stress Support neem

Moet nie Afrasia Health Stress Support neem:

- indien jy hipersensitief (allergies) is vir enige van die bestanddele van Afrasia Health Stress Support (sien Wat Afrasia Health Stress Support bevat).
- as jy medisyne gebruik wat die sterkte van jou liggaam se immuunstelsel onderdruk of verminder.

Waaskuwings en voorsorgmaatreëls

Indien jou algemene gesondheid verswak gedurende die gebruik van Afrasia Health Stress Support, raadpleeg jou gesondheidsorgverskaffer.

Ander medisyne en Afrasia Health Stress Support

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Raadpleeg jou gesondheidsorgverskaffer voordat jy Afrasia Health Stress Support neem, as jy tans barbiturate gebruik (medisyne wat as 'n sentrale senuweestelsel depressant werk), aangesien die kombinasie die kalmerende effek kan verhoog.

Afrasia Health Stress Support met voedsel en drank

Sien afdeling 3 (Hoe om Afrasia Health Stress Support te neem).

Swangerskap, borsvoeding en vrugbaarheid

Die veiligheid en effektiwiteit van Afrasia Health Stress Support kapsules tydens swangerskap en borsvoeding is nie vasgestel nie. Hierdie medisyne moet dus nie tydens swangerskap en borsvoeding 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

Dit is onwaarskynlik dat Afrasia Health Stress Support 'n invloed sal hê op jou vermoë om 'n voertuig te bestuur en masjiene te gebruik. Dit is nie altyd moontlik om te voorspel in watter mate Afrasia Health Stress 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 Stress Support op hulle sal hê.

3. Hoe om Afrasia Health Stress Support te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem Afrasia Health Stress 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 kapsule twee keer per dag saam met water, voor etes, of soos voorgeskryf deur jou gesondheidsorgverskaffer.

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

4. Moontlike nuwe-effekte
Afrasia Health Stress Support kan nuwe- effekte hê.
Ashwagandha: Gereelde nuwe-effekte kan die volgende insluit: ligte- tot matige slaperigheid wat vir 'n kort rukkie duur, ongemak in die boonste spysverteringskanaal (wat kan voorkom as boonste buik, spysvertering of opgeblasenheid) en diarree .
Bacopa: Gereelde nuwe-effekte kan griepagtige simptome, gastro-intestinale irritasie, naarheid, droë mond, verhoogde dermbewegings en spierswakheid of pyn insluit.

Nie alle nuwe-effekte wat vir Afrasia Health Stress 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 Stress Support neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

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

Aanmelding van nuwe-effekte
Indien jy nuwe-effekte ondervind, bespreek dit met jou dokter of apteker.
Jy kan ook nuwe-effekte by info@grischo.co.za rapporteer.
Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van Afrasia Health Stress Support te verskaf.

- 5. Hoe om Afrasia Health Stress 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.
 - Hou die houer dig toe.
 - 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 Stress Support bevat

Elke kapsule bevat die volgende aktiewe bestanddele:	
Withania somnifera (Ashwagandha)	250 mg
Ocimum tenuiflorum (Holy Basil) (blaar uitreksel)	50 mg
Bacopa monnieri (Bacopa/Brahmi) (10% bacoside)	50 mg

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

Hoe Afrasia Health Stress Support lyk en die inhoud van die verpakking
'n Wit plastiekbottel met 'n skroefdp, drukseël, verpak in 'n karton.
Elke bottel bevat 60 wit kapsules.

Houer van Registrasiesertifikaat
Grischo (Pty) Ltd
Unit 2B 80A Concorde Road East, Bedfordview, 2007
info@grischo.co.za

Hierdie inligtingsblad is hersien in
Sal met registrasie deur die SAHPRA toegeken word.

Registrasienommer
Sal met registrasie deur die SAHPRA toegeken word.

Afrasia Health Stress Support

PROFESSIONAL INFORMATION

SCHEDULING STATUS
Unscheduled

PROPRIETARY NAME AND DOSAGE FORM
Afrasia Health Stress Support capsules

COMPOSITION
Each capsule contains:
Withania somnifera (Ashwagandha) 250 mg
Ocimum tenuiflorum (Holy Basil) (leaf extract) 50 mg
Bacopa monnieri (Bacopa/Brahmi) (10% bacoside) 50 mg

Other excipients: Microcrystalline cellulose, silicon dioxide, magnesium stearate.
Capsules are free of gluten, sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION
Category D Complementary Medicine
33.8 Other Herbal

PHARMACOLOGICAL ACTION
Ashwagandha as a traditional use medicine is reported to have sedative and adaptogenic properties.
Bacopa as a traditional use medicine is used for its antioxidant, adaptogenic, anxiolytic and possible cognitive-enhancing effect.
Holy Basil is a traditional medicinal herb, which acts on the central nervous system to bring about a mild anxiolytic action.

INDICATIONS
Afrasia Health Stress Support is used as a traditional supplement to assist in relief of occasional stress.

CONTRAINDICATIONS
Hypersensitivity (allergy) to any of the ingredients in the formulation.
Ashwagandha is contraindicated with immuno-suppressant medication.

WARNINGS AND SPECIAL PRECAUTIONS
If your general health worsens while taking Afrasia Health Stress Support, please consult your healthcare provider.

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

INTERACTIONS
Ashwagandha is contraindicated with immuno-suppressant medication. It may have an additive effect with barbiturates, and use in combination with sedatives should be avoided.

PREGNANCY AND LACTATION
The safety and efficacy of Afrasia Health Stress 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 Stress Support capsules will affect the ability to drive or operate machines.

DOSAGE AND DIRECTIONS FOR USE
As a traditional herbal dietary supplement for adults, take one capsule twice daily with water before meals, or as directed by your healthcare provider.

SIDE EFFECTS
Ashwagandha: Frequent side effects include mild to moderate and transient drowsiness, upper GI discomfort and diarrhoea.
Bacopa: Frequent side effects may include flu-like symptoms, GI irritation, nausea, dry mouth, increased intestinal motility and muscle fatigue.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Treatment is symptomatic and supportive.

IDENTIFICATION
White vegecap.

PRESENTATION
White plastic bottle containing 60 capsules, in a 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 2B 80A Concorde Road East, Bedfordview, 2007

CUSTOMER CARE
info@grischo.co.za

DATE OF PUBLICATION OF THIS PACKAGE INSERT
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