

## Afrasia Health Immune Support

### PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

Unscheduled

#### Afrasia Health Immune Support tablets

Ascorbic acid (Vitamin C)  
Zinc lactate trihydrate  
Nicotinamide (Vitamin B3)  
Cholecalciferol (Vitamin D3)  
**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 Immune Support is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Afrasia Health Immune 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 Immune Support is and what it is used for
2. What you need to know before you take Afrasia Health Immune Support
3. How to take Afrasia Health Immune Support
4. Possible side effects
5. How to store Afrasia Health Immune Support
6. Contents of the pack and other information

#### 1. What Afrasia Health Immune Support is and what it is used for

Afrasia Health Immune Support is a multivitamin and mineral supplement which helps to maintain your immune system.

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

##### Do not take Afrasia Health Immune Support:

- if you are hypersensitive (allergic) to any of the ingredients of Afrasia Health Immune Support (listed in section 6).
- Not suitable for use in children younger than 14 years, unless on the advice of your healthcare provider.

#### Warnings and precautions

If you suffer from any serious ailments or conditions, please check with your healthcare provider before taking this medicine.

Consult your healthcare provider prior to use if you:

- currently have or have previously had peptic ulcers,
- are diabetic as very high doses of Vitamin C may interfere with tests for sugar in the urine,
- have gout,
- have liver or kidney problems,
- currently have or have previously had kidney stones, as high doses of Vitamin C may increase the risk of kidney stones in the urinary tract,
- have multiple sclerosis,
- have heart disease,
- have a genetic disorder called G6PD deficiency as high doses of Vitamin C may cause haemolytic anaemia, and
- have a high calcium level in your blood.

#### Other medicines and Afrasia Health Immune Support

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) Please check with your healthcare provider before taking this medicine, if you are taking:

- carbamazepine,
- medication that may harm your liver,
- anticoagulants and antiplatelets,
- thiazide diuretics,
- calcium-containing medicines,
- indinavir,
- magnesium-containing antacids, and
- digoxin.

Vitamin C may affect the metabolism of the following: protease inhibitors, estrogen, fluphenazine, warfarin and statins.

Zinc supplements reduce the absorption of copper, ciprofloxacin, iron, norfloxacin, penicillamine and tetracyclines.

#### Afrasia Health Immune Support with food and drink

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

#### Pregnancy, breastfeeding and fertility

The safety and efficacy of Afrasia Health Immune Support tablets during pregnancy and lactation have not been established.

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

Afrasia Health Immune Support is unlikely to have an effect on your ability to drive a vehicle and use machines. It is not always possible to predict to what extent Afrasia Health Immune 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 Immune Support affects them.

#### 3. How to take Afrasia Health Immune Support

Do not share your medicines with any other person. Always take Afrasia Health Immune 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 and children over 14 years: Take 1 tablet daily after food, or as directed by your healthcare provider.

#### If you take more Afrasia Health Immune 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 Immune Support

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

#### 4. Possible side effects

Afrasia Health Immune Support can have side effects.  
Vitamin C: Side effects may include gastrointestinal disturbances such as indigestion, nausea, vomiting, diarrhoea and stomach cramps.  
Zinc: Side effects may include stomach pain, indigestion, nausea, vomiting, diarrhoea, stomach irritation, a metallic taste in the mouth and a burning pain in your upper abdomen.  
Vitamin B3: Side effects may include faintness, headache, stomach cramps and itching.  
Vitamin D3: Side effects are dose related, and may include hypercalcaemia (high blood calcium levels) and anaemia.

Not all side effects reported for Afrasia Health Immune Support are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Afrasia Health Immune 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 Immune Support.

#### 5. How to store Afrasia Health Immune 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 Immune Support contains  
Each tablet contains the following active ingredients:

Ascorbic acid (Vitamin C)	1000 mg
Zinc lactate trihydrate	20 mg
providing Zinc (elemental)	4,5 mg
Nicotinamide (Vitamin B3)	15 mg
Cholecalciferol (Vitamin D3)	800 iu

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

#### What Afrasia Health Immune 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 30 white oval tablets.

#### 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

## PASIËNTINLIGTINGSBLAD

### SKEDULERINGSSTATUS

Ongeskeduleer

#### Afrasia Health Immune Support tablette

Askorbiensuur (Vitamiën C)  
Sinklaktaat-trihidraat  
Nikotinamied (Vitamiën B3)  
Cholecalciferol (Vitamiën D3)  
**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 Immune Support is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy Afrasia Health Immune 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 Immune Support is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy Afrasia Health Immune Support neem
3. Hoe om Afrasia Health Immune Support te neem
4. Moontlike nuwe-effekte
5. Hoe om Afrasia Health Immune Support te bêre
6. Inhoud van die verpakking en ander inligting

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

Afrasia Health Immune Support is 'n multivitamiën- en mineraalaanvulling wat jou immuunstelsel help behou.

#### 2. Wat jy moet weet voordat jy Afrasia Health Immune Support neem

- indien jy hipersensitief (allergies) is vir enige van die bestanddele van Afrasia Health Immune Support (sien **Wat Afrasia Health Immune Support bevat**)
- Nie geskik vir gebruik by kinders jonger as 14 jaar nie, tensy op advies van jou gesondheidsorgverskaffer.

#### Waaskuwings en voorsorgmaatreëls

As jy aan ernstige kwale of toestande ly, moet jy jou gesondheidsorgverskaffer raadpleeg voordat jy hierdie medisyne gebruik. Raadpleeg jou gesondheidsorgverskaffer voor gebruik as jy:

- tans peptiese ulkuse het of voorheen gehad het,
- 'n diabeet is, aangesien baie hoë dosisse van Vitamiën C die toetse vir suiker in die urine kan beïnvloed,
- aan jîg ly,
- lewer- of nierprobleme het,
- tans nierstene het of voorheen gehad het, aangesien hoë dosisse van Vitamiën C die risiko van nierstene in die urieneweg kan verhoog,
- aan veelvuldige sklerose ly,
- aan hartsiëkte ly,
- 'n genetiese afwyking het wat G6PD-tekort genoem word, aangesien hoë dosisse Vitamiën C hemolitiese anemie kan veroorsaak , en
- 'n hoë kalsiumvlak in u bloed het.

#### Ander medisyne en Afrasia Health Immune Support

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

Raadpleeg jou dokter voordat jy hierdie medisyne gebruik, indien jy die volgende gebruik:

- karbamazepien,
- medikasie wat jou lewer kan skaad,
- antikoagulante en antiplatelets,
- tiasied-diuretika,
- kalsiumbevattende medisyne,
- indinavir,
- magnesium-bevattende teensuurmiddels, en
- digoksien.

Vitamiën C kan die metabolisme van die volgende beïnvloed: protease-inhibeerders, estrogen, flufenasien, warfarin en statiene. Sink-aanvullings verminder die opname van koper, ciprofloxasien, yster, norfloxacin, penisillamien en tetrasiklien.

#### Afrasia Health Immune Support met voedsel en drank

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

#### Swangerskap, borsvoeding en vrugbaarheid

Die veiligheid en effektiwiteit van Afrasia Health Immune Support tablette tydens swangerskap en borsvoeding is nie vasgestel 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 Immune 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 Immune Support die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet toesien dat hulle nie aan buitengewone aktiwiteite deelneem nie, totdat hulle bewus is van die uitwerking wat Afrasia Health Immune Support op hulle sal hê.

### **3. Hoe om Afrasia Health Immune Support te neem**

Moet nie jou medisyne met enige ander persoon deel nie. Neem Afrasia Health Immune 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 en kinders ouer as 14 jaar: Neem 1 tablet daaglik na ete, of soos aanbeveel deur jou gesondheidsorgverskaffer.

### **As jy meer Afrasia Health Immune 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 Immune Support te neem**

Moet nie 'n dubbele dosis neem om vir die vergete dosis op te maak nie.

### **4. Moontlike nuwe-effekte**

Afrasia Health Immune Support kan nuwe- effekte hê. Vitamien C: nuwe-effekte kan gastro-intestinale verstourings insluit soos slegte spysvertering, naarheid, braking, diarree en maagkrampe. Sink: nuwe-effekte kan insluit maagpyn, slegte spysvertering, naarheid, braking, diarree, maagirritasie, 'n metaalagtige smaak in die mond en brandpyn in die boonste buik. Vitamien B3: nuwe-effekte kan insluit flouheid, hoofpyn, maagkrampe en jeuk. Vitamien D3: nuwe-effekte hou verband met dosisse, en dit kan hiperkalsemie (hoë kalsiumvlakke in die bloed) en bloedarmoede insluit.

Nie alle nuwe-effekte wat vir Afrasia Health Immune 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 Immune 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 Immune Support te verskaf.

### **5. Hoe om Afrasia Health Immune 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 houder dig toe.
- Moet nie gebruik word na die vervaldatum wat op die houder 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 Immune Support bevat**

Elke tablet bevat die volgende aktiewe bestanddele:

Askorbiesuur (Vitamien C)	1000 mg
Sinklakaat-trihidraat	20 mg
verskaf Sink (elementêr)	4,5 mg
Nikotinamied (Vitamien B3)	15 mg
Cholecalciferol (Vitamien D3)	800 iu

Die ander bestanddele is mikrokristallyne sellulose, silikondioksied, magnesiumstearaat.

Die tablette bevat geen gluten, suiker en laktose.

#### **Hoe Afrasia Health Immune Support lyk en die inhoud van die verpakking**

'n Wit plastiekbottel met 'n skroefdoop, drukseël, verpak in 'n karton. Elke bottel bevat 30 wit ovaal tablette.

#### **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.

#### **Registrasienuommer**

Sal met registrasie deur die SAHPRA toegeken word.

### **Afrasia Health Immune Support**

### **PROFESSIONAL INFORMATION**

#### **SCHEDULING STATUS**

Unscheduled

#### **PROPRIETARY NAME AND DOSAGE FORM**

Afrasia Health Immune Support tablets

#### **COMPOSITION**

Each tablet contains:

Ascorbic acid (Vitamin C)	1000 mg
Zinc lactate trihydrate	20 mg
providing Zinc (elemental)	4,5 mg
Nicotinamide (Vitamin B3)	15 mg
Cholecalciferol (Vitamin D3)	800 iu

Other excipients: Microcrystalline cellulose, silicon dioxide, magnesium stearate.

Tablets are free of gluten, sugar and lactose.

#### **PHARMACOLOGICAL CLASSIFICATION**

Category D Complementary Medicine: Health Supplements  
34.12 Multi substance formulation

#### **PHARMACOLOGICAL ACTION**

Vitamin C has proven antioxidant properties for the maintenance of good health, and maintains the normal function of the immune system. Vitamin C in high doses (up to 1000 mg daily) has been shown to decrease the severity and duration of the common cold. Zinc helps to maintain immune function, and contributes to the maintenance of good health. Zinc deficiency may result in an impaired immune response. Vitamin B3 is a factor in the maintenance of good health. Vitamin D3 is an essential element to maintaining good health, and contributes to the normal function of the immune system.

#### **INDICATIONS**

Afrasia Health Immune Support is a multivitamin and mineral supplement which contributes to maintaining immune function.

#### **CONTRAINDICATIONS**

Hypersensitivity to any of the ingredients in the formulation. Not suitable for use in children younger than 14 years, unless under medical supervision.

#### **WARNINGS AND SPECIAL PRECAUTIONS**

Afrasia Health Immune Support should be used with caution in patients with a history of peptic ulcer disease, and in those patients with diabetes mellitus, gout or impaired liver function. Caution should be taken when this medication is taken by patients with renal dysfunction, a history of urolithiasis, G6PD deficiency, multiple sclerosis, hypercalcaemia, and heart disease.

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

#### **INTERACTIONS**

Consult your healthcare provider if you are currently taking the following medication: carbamazepine, hepatotoxic medicine, anticoagulants, antiplatelets, thiazide diuretics, calcium-containing medicines, and indinavir. Interactions may also occur with magnesium-containing antacids, and digoxin. Vitamin C may affect the metabolism of the following: protease inhibitors, estrogen, fluphenazine, warfarin and statins. Zinc supplements reduce the absorption of copper, ciprofloxacin, iron, norfloxacin, penicillamine and tetracyclines.

#### **PREGNANCY AND LACTATION**

The safety and efficacy of Afrasia Health Immune Support tablets during pregnancy and lactation have not been established.

#### **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

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

#### **DOSAGE AND DIRECTIONS FOR USE**

Adults and children 14 years and older: Take one tablet daily after food, or as directed by your healthcare provider.

#### **SIDE EFFECTS**

Vitamin C: Side effects may include gastrointestinal disturbances such as dyspepsia, nausea, vomiting, diarrhoea and stomach cramps. Zinc: Side effects may include abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, a metallic taste and gastritis. Vitamin B3: Side effects may include faintness, headache, abdominal cramps and pruritis. Vitamin D3: Side effects are dose related, and may include hypercalcaemia and anaemia.

### **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

Treatment is symptomatic and supportive.

#### **IDENTIFICATION**

White oval tablets.

#### **PRESENTATION**

White plastic bottle containing 30 tablets, 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 THE PROFESSIONAL INFORMATION**

TBA