SFERA® BIO NUTRITION

PATIENT INFORMATION LEAFLET: SFERA TONGKAT ALI

SCHEDULING STATUS **S0**

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM
SFERA TONGKAT ALI. Each capsule contains: 500mg *Eurycoma longifolia* (Tongkat Ali) [root extract 100:1]
Suitable for vegetarians and vegans.
No added sugar.

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT
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
SFERA TONGKAT ALI is available without a doctor's prescription, for you to use as a health supplement. Nevertheless, you still need to use **SFERA TONGKAT ALI** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **SFERA TONGKAT ALI** with any other person.
- Ask your doctor or pharmacist if you need more information or advice.

What is in this leaflet

1. What **SFERA TONGKAT ALI** is and what it is used for
2. What you need to know before you use **SFERA TONGKAT ALI**
3. How to use **SFERA TONGKAT ALI**
4. Possible side effects
5. How to store **SFERA TONGKAT ALI**
6. Contents of the pack and other information

1. WHAT SFERA TONGKAT ALI IS USED FOR
SFERA TONGKAT ALI may increase muscle mass, endurance, improve athletic performance and increase in lean body mass.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SFERA TONGKAT ALI
Do not take SFERA TONGKAT ALI

- if you are hypersensitive (allergic) to any of the ingredients of **SFERA TONGKAT ALI** see section 6).
- If you have prostate cancer or a history of prostate cancer.
- If you have diseases like breast cancer, heart disease, liver disease or sleep apnoea.
- if you have a compromised immune system, Eurycoma longifolia (Tongkat Ali) may further weaken the immune function.

Warnings and precautions
Take special care with SFERA TONGKAT ALI

- if you have a medical condition or are taking prescription medication.
- If you are using hypoglycaemic agents.

Consult a health care provider if symptoms persist or worsen.
Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a health care provider.

Children and adolescents
Children and adolescents under the age of 18 years should not take **SFERA TONGKAT ALI**.

Other medicines and SFERA TONGKAT ALI
Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

- *Eurycoma longifolia* (Tongkat Ali) can reduce the levels and clinical effects of propranolol and patients are advised to discuss an appropriate dosing schedule with their health care providers.

Interactions with diseases

- *Eurycoma longifolia* (Tongkat Ali) might reduce blood glucose levels. Combined use might increase the risk for hypoglycaemia, especially in patients on insulin or oral hypoglycaemic medications. Dose adjustment for diabetes medications may be necessary.
- Patients are advised to discontinue **SFERA TONGKAT ALI** at least 2 weeks before elective surgical procedures (see section 4.4).

Interactions with foods

- Vitamins, minerals, and nutrients obtained from other sources should be taken into account when prescribing / suggesting **SFERA TONGKAT ALI.**

SFERA TONGKAT ALI with food and liquids:
Take **SFERA TONGKAT ALI** with liquids and with a meal.

Pregnancy and breastfeeding:
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 health care provider for advice before taking this medicine.

Driving and using machinery:
It is not always possible to predict to what extent **SFERA TONGKAT ALI** 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 **SFERA TONGKAT ALI** affects them.

3. HOW TO TAKE SFERA TONGKAT ALI
Do not share medicines you are taking with any other person. Always take **SFERA TONGKAT ALI** exactly as described in this leaflet or as your doctor, pharmacist or health care provider told you. Check with your doctor, pharmacist, or health care provider if you are not sure. The usual dose is:
Adults: Take one (1) capsule daily orally with a meal, or as directed by your health care provider. Do not exceed two (2) capsules per day.

If you take more SFERA TONGKAT ALI than 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 a dose of SFERA TONGKAT ALI
Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS
SFERA TONGKAT ALI can have side effects. Not all side effect reported for **SFERA TONGKAT ALI** are included in this leaflet. Orally *Eurycoma longifolia* (Tongkat Ali) is well-tolerated. Consult a health care provider if you experience any side-effects:
Gastrointestinal disorders:
Frequency unknown: Eurycoma longifolia (Tongkat Ali) can cause abdominal pain, cramping and nausea.
Nervous system disorders:
Frequency unknown: Eurycoma longifolia (Tongkat Ali) may cause restlessness, irritability, and insomnia.
Endocrine system disorders:
Frequency unknown: Eurycoma longifolia (Tongkat Ali) might increase testosterone levels, if testosterone levels are increased beyond the normal range, there is risk of testosterone side effects which could include acne, insulin resistance, hepatotoxicity, and others.

Should your general health worsen or if you experience any untoward effects while taking **SFERA TONGKAT ALI,** please consult your health care provider for advice.
If any of the following happens, stop taking **SFERA TONGKAT ALI** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth, or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **SFERA TONGKAT ALI.** You may need urgent medical attention or hospitalisation. 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 pharmacist@sfera-nutrition.co.za or 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 **SFERA TONGKAT ALI.**

5. HOW TO STORE SFERA TONGKAT ALI

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from moisture.
- Keep in the original container until ready for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What SFERA TONGKAT ALI contains
Each capsule contains:
Eurycoma longifolia (Tongkat Ali) [root, 100:1 extract providing 50 g dried herb equivalent] 500 mg

- The other ingredients are a vegetarian capsule, natural flow agent and microcrystalline cellulose.

What SFERA TONGKAT ALI looks like and contents of the pack
SFERA TONGKAT ALI capsules are clear size "0" capsules filled with a brown powder.
SFERA TONGKAT ALI: 60 capsules are packed into an amber glass bottle, with a golden plastic lid with plastic seal liner, desiccant sachet and outer protective tamperproof shrink sleeve on the cap.

Holder of Certificate of Registration
Sfera Bio Nutrition (Pty) Ltd.
5 Regency Drive, Block C, Route 21 Corporate Park, Pretoria, 0181
Telephone: 012 751 7117 | Website: www.sfera-nutrition.co.za

This leaflet was last revised in:
January 2024.

Registration number
Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information
Detailed information on this medicinal product is available from pharmacist@sfera-nutrition.co.za or www.sfera-nutrition.co.za

SFERA BIO NUTRITION

PASIËNT INLIGTINGSBLAD: SFERA TONGKAT ALI

SKEDULERING STATUS S0

PRODUKNAAM, STERKTE EN DOSEERVORM
SFERA TONGKAT ALI. Elke kapsule bevat: 500mg *Eurycoma longifolia* (Tongkat Ali) [wortel ekstrak 100:1]
Geskik vir vegetariërs en vegane.
Geen suiker bygevoeg.

KOMPLEMENTÊRE MEDISYNE: GESONDHEID AANVULLING
Hierdie ongeregistreerde medisyne is nog nie geëvalueer deur die SAHPRA vir die kwaliteit, veiligheid of vir die voorgenome gebruik nie.

Lees die hele blaadjie noukeurig deur omdat dit belangrike inligting vir u bevat.
SFERA TONGKAT ALI is beskikbaar sonder 'n dokter se voorskrif, vir u om te gebruik as 'n gesondheid aanvulling. Nogtans behoort u **SFERA TONGKAT ALI** met versigtigheid te gebruik om die beste resultate daaruit te verkry.

- Hou hierdie blaadjie. U mag dit weer wil lees.
- Moenie **SFERA TONGKAT ALI** deel met enige ander persoon nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Wat is in hierdie blaadjie

1. Wat is **SFERA TONGKAT ALI** en waarvoor word dit gebruik
2. Wat u moet weet voordat u **SFERA TONGKAT ALI** gebruik
3. Hoe om **SFERA TONGKAT ALI** te gebruik
4. Moontlike newe-effekte
5. Hoe om **SFERA TONGKAT ALI** te berg
6. Inhoud van die verpakking en ander inligting

1. WAT IS SFERA TONGKAT ALI EN WAARVOOR WORD DIT GEBRUIK
SFERA TONGKAT ALI mag spiermassa, uithouvermoë verhoog, atletiese prestasie verbeter en gesonde liggaamsmassa verhoog.

2. WAT U MOET WEET VOORDAT U SFERA TONGKAT ALI GEBRUIK
Moenie SFERA TONGKAT ALI neem nie:

- indien u hipersensitief (allergies) is vir enige van die bestanddele van **SFERA TONGKAT ALI** (sien afdeling 6).
- as jy prostaatkanker of 'n geskiedenis van prostaatkanker het.
- as jy siektes soos borskanker, hartsiekte, lewersiekte of slaap apnee het.
- as jy 'n swak immuunstelsel het, kan Eurycoma longifolia (Tongkat Ali) die immuunfunksie verder verswak.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met SFERA TONGKAT ALI

- indien u 'n mediese siekte het of voorskrif medisyne neem.
- Indien u hipoglisemiese middels gebruik.

Raadpleeg u gesondheidsorgverskaffer indien die simptome aanhou of vererger. Voedingsaanvulling behoort nie 'n gebalanseerde dieet te vervang nie. Moenie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

Kinders en adolessente
Kinders en adolessente onder die ouderdom van 18 jaar moet nie **SFERA TONGKAT ALI** gebuik nie.

Ander medisyne en SFERA TONGKAT ALI
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- *Eurycoma longifolia* (Tongkat Ali) kan die vlakke en kliniese effekte van propranodol verminder en pasiënte word aangeraai om 'n toepaslike doseringskedule met hul gesondheidsorgverskaffers te bespreek.

Interaksies met siektes

- *Eurycoma longifolia* (Tongkat Ali) kan bloedglukosevlakke verlaag. Gekombineerde gebruik kan die risiko vir lae bloed suiker verhoog, veral by pasiënte wat insulien of orale hipoglisemiese medikasie gebruik. Dosis aanpassing vir diabetes medikasie kan nodig wees.
- Pasiënte word aangeraai om **SFERA TONGKAT ALI** ten minste 2 weke voor elektiewe chirurgiese operasies te staak (sien afdeling 4.4).

Interaksies met voedsel

- Vitamiene, minerale en voedingstowwe wat van ander bronne verkry word, moet in ag geneem word wanneer **SFERA TONGKAT ALI** voorgeskryf / voorgestel word.

SFERA TONGKAT ALI saam met voedsel en vloeistowwe:
Neem **SFERA TONGKAT ALI** met vloeistof saam met 'n maaltyd.

Swangerskap en borsvoeding:
Indien u swanger is of borsvoed, dink dat u swanger is of van plan is om swanger te raak, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer voordat u hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie:
Dit is nie altyd moontlik om te voorspel in watter mate **SFERA TONGKAT ALI** 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 mate waarin **SFERA TONGKAT ALI** hulle beïnvloed.

3. HOE OM SFERA TONGKAT ALI TE GEBRUIK
Moenie medisyne wat u neem met enige ander persoon deel nie. Neem altyd **SFERA TONGKAT ALI** presies soos voorgeskryf in hierdie pamflet of soos u dokter, apteker of gesondheidsorgverskaffer vir u gesê het. Raadpleeg u dokter, apteker of gesondheidsorgverskaffer as u nie seker is nie. Die gewone dosis is:
Volwassenes: Neem een (1) kapsules daagliks oraal met water met 'n maaltyd, of soos aangedui deur u gesondheidsorgverskaffer. Moenie twee (2) kapsules per dag oorskry nie.

Indien u meer SFERA TONGKAT ALI neem as wat u behoort te neem:
In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gif hulp sentrum.

Indien u vergeet om 'n dosis SFERA TONGKAT ALI te neem:
Moenie 'n dubbele dosis neem om die vergete enkel dosis in te haal nie.

4. MOONTLIKE NEWE EFFEKTE
SFERA TONGKAT ALI kan newe effekte hê.
Nie al die newe effekte aangemeld vir **SFERA TONGKAT ALI** is ingesluit in hierdie blaadjie nie. Oraal word *Eurycoma longifolia* (Tongkat Ali) goed verdra. Raadpleeg 'n gesondheidsorgverskaffer as u enige newe-effekte ervaar:
Gastrointestinale afwykings:
Frekwensie onbekend: Eurycoma longifolia (Tongkat Ali) kan buikpyn, krampe en naarheid veroorsaak.
Senuweestelsel afwykings:
Frekwensie onbekend: Eurycoma longifolia (Tongkat Ali) kan rusteloosheid, prikkelbaarheid en slapeloosheid veroorsaak.
Afwykings van die endokriene stelsel:
Frekwensie onbekend: Eurycoma longifolia (Tongkat Ali) kan testosteroon vlakke verhoog, as testosteroon vlakke verby die normale omvang toeneem, is daar risiko van testosteroon newe-effekte wat aknee, insulien weerstand, lewer toksisiteit en ander kan insluit.

Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar wanneer u **SFERA TONGKAT ALI** neem.
As enige van die volgende gebeur, moet u ophou om **SFERA TONGKAT ALI** te neem en u dokter onmiddellik inlig of na die ongevalle-afdeling in u naaste hospitaal gaan:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.
- Uitslag of jeuk.
- Floute ervaar.

Dit is alles baie ernstige newe-effekte. As u dit het, kan u 'n ernstige reaksie op **SFERA TONGKAT ALI** hê. U mag dringend mediese hulp of hospitalisasie benodig. Stel u dokter of apteker in kennis as u newe-effekte opmerk wat nie in hierdie pamflet genoem word nie.

Rapportering van newe-effekte
As u newe-effekte kry, moet u met u dokter of apteker praat. U kan ook newe-effekte aan pharmacist@sfera-nutrition.co.za of SAHPRA rapporteer via die **"6.04 Adverse Drug Reaction Reporting Form"**, aanlyn onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **SFERA TONGKAT ALI** voorsien.

5. HOE OM SFERA TONGKAT ALI TE BERG

- Hou alle medisyne buite bereik van kinders.
- Berg by of benede 25 °C.
- Beskerm teen vog.
- Berg in die oorspronklike houer totdat gereed vir gebruik.
- Moenie in 'n badkamer berg nie.
- Moenie gebruik na die vervaldatum soos op die bottel aangedui nie.
- Neem alle ongebruikte medisyne terug na u apteker toe.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING
Wat SFERA TONGKAT ALI bevat
Elke kapsule bevat:
Eurycoma longifolia (Tongkat Ali) [wortel ,100:1 ekstrak verskaf 50 g gedroogte kruie ekwivalent] 500 mg

- Die ander bestanddele is: 'n Vegetariese kapsule, natuurlike vloei middel en mikrokristallyne sellulose.

SFERA TONGKAT ALI lyk en die inhoud van die verpakking
SFERA TONGKAT ALI kapsules is deursigtige grootte "0" kapsules gevul met 'n bruin poeier.
SFERA TONGKAT ALI: 60 kapsules word verpak in 'n amber glasbottel, met 'n goudkleurige deksel met 'n druk-seël voering, silika jel sakkie en 'n beskermende sellofaan krimp-omhulsel om die deksel.

Houer van Registrasiesertifikaat
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Hierdie pamflet is laas hersien in
Januarie 2024.

Registrasie nommer
Sal gealokeer word deur SAHPRA tydens registrasie.

Toegang tot die ooreenstemmende professionele inligting
Gedetailleerde inligting oor hierdie medisyne is beskikbaar by pharmacist@sfera-nutrition.co.za of www.sfera-nutrition.co.za