

PATIENT INFORMATION LEAFLET: SFERA TULSI

SCHEDULING STATUS **SO**

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

SFERA TULSI. Each capsule contains: 500 mg *Ocimum sanctum* (Tulsi / Holy Basil) [leaves, extract standardised for a minimum of 2% ursolic acid]. No added sugar.

Suitable for vegetarians and vegans.

COMPLEMENTARY MEDICINE: AYURVEDIC/UNANI 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 SFERA TULSI is available without a doctor's prescription, for you to use as a health supplement. Nevertheless, you still need to use SFERA TULSI carefully to get the best results from it.

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

What is in this leaflet

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

1. WHAT SFERA TULSI IS USED FOR

SFERA TULSI may aid digestion and stimulate appetite.

SFERA TULSI may assist to increase energy and resistance to stress (in case of mental and physical fatigue related to stress).

SFERA TULSI is a source of antioxidants.

SFERA TULSI may assist (as an expectorant and/or demulcent) to help relieve coughing.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SFERA TULSI

Do not take SFERA TULSI:

- If you are hypersensitive (allergic) to any of the ingredients of SFERA TULSI (see section 6).

Warnings and precautions

Consult your doctor prior to use, especially if you have a medical condition or are taking prescription medication.

Take special care with SFERA TULSI

- If you have a heart condition.
 - If you have diabetes.
 - If you have a medical condition or are taking prescription medication.
- Consult a health care provider if symptoms persist or worsen.

Children and adolescents

Children and adolescents under the age of 18 years should not take SFERA TULSI.

Other medicines and SFERA TULSI

Consult a health care provider prior to use if you are taking heart or blood pressure medication, or blood thinners.

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

SFERA TULSI with food and drink

Take SFERA TULSI before or after a meal with water.

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 TULSI 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 TULSI affects them.

3. HOW TO TAKE SFERA TULSI

Do not share medicines you are taking with any other person.

Always take SFERA TULSI 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 two (2) capsules daily orally with a meal, or as directed by your health care provider.

If you take more SFERA TULSI than you should:

In the event of overdose, 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 TULSI

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

4. POSSIBLE SIDE EFFECTS

SFERA TULSI can have side effects.

Not all side effects reported for SFERA TULSI is included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SFERA TULSI, please consult your health care provider for advice.

If any of the following happens, stop taking SFERA TULSI 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 TULSI. 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 TULSI.

5. HOW TO STORE SFERA TULSI

- 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 TULSI contains

Each capsule contains:

Ocimum sanctum (Tulsi / Holy Basil) [leaves, extract standardised for a minimum of 2% ursolic acid].

500 mg

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

What Sfera Tulsi looks like and contents of the pack

SFERA TULSI capsules are clear size "0" capsules filled with a brown powder.

SFERA TULSI: 60 capsules are packed into an amber glass bottle, with a golden 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

PASIENT INLIGTINGSBLAD: SFERA TULSI

SKEDULERING STATUS S0

PRODUKNAAM, STERKTE EN DOSEERVORM

SFERA TULSI. Elke kapsule bevat: 500 mg *Ocimum sanctum* (Tulsi / Holy Basil) [blare, uittreksel gestandaardiseer vir 'n minimum van 2% ursolic suur]. Geen suiker bygevoeg. Geskik vir vegetariërs en vegane.

KOMPLEMENTÊRE MEDISYNE: GESONDHEID AANVULLING

Hierdie ongeregistreerde medisyne is nog nie geëvalueer deur die SAHPRA vir die kwaliteit, veiligheid of vir die voorgename gebruik nie.

Lees die hele blaadjie noukeurig deur omdat dit belangrike inligting vir u bevat.

SFERA TULSI is beskikbaar sonder 'n dokter se voorskrif, vir u om te gebruik as 'n gesondheid aanvulling. Nogtans behoort u **SFERA TULSI** met versigtigheid te gebruik om die beste resultate daaruit te verkry.

- Hou hierdie blaadjie. U mag dit weer wil lees.
- Moenie **SFERA TULSI** 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 TULSI** en waarvoor word dit gebruik
2. Wat u moet weet voordat u **SFERA TULSI** gebruik
3. Hoe om **SFERA TULSI** te gebruik
4. Moontlike nuwe-effekte
5. Hoe om **SFERA TULSI** te berg
6. Inhoud van die verpakking en ander inligting

1. WAT IS SFERA TULSI EN WAARVOOR WORD DIT GEBRUIK

SFERA TULSI mag vertering verbeter en eetlust stimuleer. **SFERA TULSI** mag help om energie en weerstand teen stres te verhoog (in die geval van geestelike en fisiese moegheid wat met stres verband hou). **SFERA TULSI** is 'n bron van antioksidante. **SFERA TULSI** mag help (as 'n ekspektorant en/of kalmeermiddel) om hoest te help verlig.

2. WAT U MOET WEET VOORDAT U SFERA TULSI GEBRUIK

Moenie **SFERA TULSI** neem nie:

- indien u hipersensitief (allergies) is vir enige van die bestanddele van **SFERA TULSI** (sien afdeling 6).

Waarskuwings en voorsorgmaatreëls

Raadpleeg u dokter voordat u **SFERA BACOPIN** begin gebruik, veral as u 'n mediese toestand het of voorskryfmedisyne gebruik.

Neem spesiale sorg met **SFERA TULSI**

- As jy 'n hartkwaal het.
 - As jy diabetes het.
 - indien u 'n mediese siekte het of voorskryf medisyne neem
- Raadpleeg u gesondheidsorgverskaffer indien die simptome aanhou of vererger.

Kinders en adolessente

Kinders en adolessente onder die ouderdom van 18 jaar moet nie **SFERA TULSI** gebruik nie.

Ander medisyne en **SFERA TULSI**

Raadpleeg u gesondheidsorgverskaffer indien u enige hart of bloeddruk medikasie, of bloedverduiners gebruik. Vertel altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (dit sluit alle aanvullende of tradisionele medisyne in).

SFERA TULSI saam met voedsel en vloeistowwe

Neem **SFERA TULSI** voor of na 'n maaltyd met water.

Swangerskap en borsvoeding

Indien u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te kry, 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 TULSI** 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 TULSI** hulle beïnvloed.

3. HOE OM SFERA TULSI TE GEBRUIK

Moenie medisyne wat u neem met enige ander persoon deel nie. Neem altyd **SFERA TULSI** 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 twee (2) kapsules daaglik oraal met water met 'n maaltyd, of soos aangedui deur u gesondheidsorgverskaffer.

Indien u meer **SFERA TULSI** 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 TULSI** te neem

Moenie 'n dubbele dosis neem om die vergete enkel dosis in te haal nie.

4. MOONTLIKE NUWE EFFEKTE

SFERA TULSI kan nuwe effekte hê.

Nie al die nuwe effekte aangemeld vir **SFERA TULSI** is ingesluit in hierdie blaadjie nie. Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar wanneer u **SFERA TULSI** neem. As enige van die volgende gebeur, moet u ophou om **SFERA TULSI** 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 nuwe-effekte. As u dit het, kan u 'n ernstige reaksie op **SFERA TULSI** hê. U mag dringend mediese hulp of hospitalisasie benodig. Stel u dokter of apteker in kennis as u nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie.

Rapportering van nuwe-effekte

As u nuwe-effekte kry, moet u met u dokter of apteker praat. U kan ook nuwe-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 nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **SFERA TULSI** voorsien.

5. HOE OM SFERA TULSI 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 TULSI** bevat

Elke kapsule bevat:

- *Ocimum sanctum* (Tulsi / Holy Basil) [blare, uittreksel gestandaardiseer vir 'n minimum van 2% ursolic suur]. 500 mg
- Die ander bestanddele is: 'n Vegetariese kapsule, natuurlike vloeï middel en mikrokristallyne sellulose.

SFERA TULSI lyk en die inhoud van die verpakking

SFERA TULSI kapsules is deursigtige grootte "0" kapsules gevul met 'n bruin poeier. **SFERA TULSI** 60 kapsules word verpak in 'n amber glasbottel, met 'n goue deksel met 'n druk-seël voering, droogmiddelsakkie en 'n beskermende krimp-omhulsel om die deksel.

Houer van Registrasiesertifikaat

Sfera Bio Nutrition (Pty) Ltd.
5 Regency Ryaan, Block C,
Route 21 Corporate Park,
Pretoria, 0181
Telefoon: 012 751 7117
Webwerf: www.sfera-nutrition.co.za

Hierdie pamflet is laas hersien in

Januarie 2024.

Registrasienommer

Sal geallokeer word deur SAHPRA tydens registrasie.

Toegang tot die ooreenstemmende professionele inligting

Getetailleerde inligting oor hierdie medisyne is beskikbaar by pharmacist@sfera-nutrition.co.za of www.sfera-nutrition.co.za