

## PATIENT INFORMATION LEAFLET: SFERA GYMNEMA

### SCHEDULING STATUS **[S0]**

#### PRODUCT NAME, STRENGTH, AND PHARMACEUTICAL FORM

**SFERA GYMNEMA.** Each capsule contains: 300 mg *Gymnema Sylvestre* (Gymnema) [leaves, extract standardised for a minimum of 75% gymnemic acids].

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 GYMNEMA** is available without a doctor's prescription, for you to use as a health supplement. Nevertheless, you still need to use **SFERA GYMNEMA** carefully to get the best results from it.

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

#### What is in this leaflet

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

#### 1. WHAT SFERA SHATAVARI IS USED FOR

**SFERA GYMNEMA** may assist in the management of blood sugar levels. **SFERA GYMNEMA** may improve the metabolism of carbohydrates.

#### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE SFERA GYMNEMA

##### Do not take **SFERA GYMNEMA**:

- if you are hypersensitive (allergic) to any of the ingredients of **SFERA GYMNEMA** (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 GYMNEMA**:

- Low blood sugar levels.
- 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 GYMNEMA**.

#### Other medicines and **SFERA GYMNEMA**

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

Consult a health care provider if you are taking:

- Anti-diabetic medication or insulin. Caution is advised when using medications that may also lower blood sugar levels. Patients taking drugs for diabetes by mouth or insulin should be monitored closely by a qualified health care provider. Medication adjustments may be necessary.
- Cholesterol Medication. Increased effects may occur when taken in combinations with drugs that lower cholesterol such as 'statins'.
- Weight loss medication.

#### **SFERA GYMNEMA** with food and drink

Take **SFERA GYMNEMA** 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 GYMNEMA** 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 GYMNEMA** affects them.

#### 3. HOW TO TAKE SFERA GYMNEMA

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

Always take **SFERA GYMNEMA** 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 twice a day orally, with meals, or as directed by your health care provider.

#### If you take more **SFERA GYMNEMA** 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 GYMNEMA**

Take your next dose at the normal time. Do not take a double dose to make up for forgotten individual doses.

#### 4. POSSIBLE SIDE EFFECTS

**SFERA GYMNEMA** can have side effects. Not all side effect reported for **SFERA GYMNEMA** are included in this leaflet. Tell your doctor if you notice any of the following: Side effect occurring less frequently: hypoglycaemia (low blood sugar). Should your general health worsen or if you experience any untoward effects while taking **SFERA GYMNEMA**, please consult your health care provider for advice. If any of the following happens, stop taking **SFERA GYMNEMA** 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 GYMNEMA**. 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 GYMNEMA**.

#### 5. HOW TO STORE SFERA GYMNEMA

- 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 GYMNEMA** contains

Each capsule contains:

- *Gymnema Sylvestre* (Gymnema) [leaves, extract standardised for a minimum of 75% gymnemic acids]. 300 mg
- The other ingredients are a vegetarian capsule, natural flow agent and microcrystalline cellulose.

##### What **SFERA GYMNEMA** looks like and contents of the pack

**SFERA GYMNEMA** capsules are clear size "0" capsules filled with a brown powder. **SFERA GYMNEMA**: 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](http://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](http://www.sfera-nutrition.co.za)

## PASIËNT INLIGTINGSBLAD: SFERA GYMNEMA

### SKEDULERING STATUS SO

#### PRODUKNAAM, STERKTE EN DOSEERVORM

**SFERA GYMNEMA.** Elke kapsule bevat 300 mg *Gymnema Sylvestre* (Gymnema) [blare, uitreksel gestandaardiseer vir 'n minimum van 75% gimneemiese sure]. Geen suiker bygevoeg. Geskik vir vegetariërs en vegane.

#### KOMPLEMENTÊRE MEDISYNE: AYURVEDIC/UNANI MEDISYNE

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

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

#### 1. WAT IS SFERA GYMNEMA EN WAARVOOR WORD DIT GEBRUIK

**SFERA GYMNEMA** mag help met die hantering van bloedsuikervlakke. **SFERA GYMNEMA** mag die metabolisme van koolhidrate verbeter.

#### 2. WAT U MOET WEET VOORDAT U SFERA GYMNEMA GEBRUIK

Moenie **SFERA GYMNEMA** neem nie:

- indien u hipersensitief (allergies) is vir enige van die bestanddele van **SFERA GYMNEMA** (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 GYMNEMA**:

- As jy lae bloedsuikervlakke het
  - As jy suikersiekte 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 GYMNEMA** gebruik nie.

#### Ander medisyne en **SFERA GYMNEMA**:

- Vertel altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in.) Raadpleeg 'n gesondheidsorgverskaffer voor gebruik indien u die volgende medikasie neem:
- Anti-diabetiese medikasie of insulien. Omsigtigheid word aangerai wanneer medikasie gebruik word wat ook bloedsuikervlakke kan verlaag. Pasiënte wat dwelms vir diabetes per mond of insulien neem, moet noukeurig deur 'n gekwalifiseerde gesondheidsorgverskaffer gemonitor word. Medikasie aanpassings mag nodig wees.
  - Cholesterol medikasie. Verhoogde effekte voorkom wanneer dit in kombinasie met medisyne geneem word wat cholesterol verlaag, soos 'statiene'.
  - Gewigsverlies medikasie.

#### **SFERA GYMNEMA** saam met voedsel en vloeistowwe

Neem **SFERA GYMNEMA** 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 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 GYMNEMA** 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 GYMNEMA** hulle beïnvloed.

#### 3. HOE OM SFERA GYMNEMA TE GEBRUIK

Moenie medisyne wat u neem met enige ander persoon deel nie.

Neem altyd **SFERA GYMNEMA** 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:

**Volwasse:** Neem een (1) kapsule twee keer per day oraal, na etes, of soos aangedui deur u gesondheidsorgverskaffer.

#### Indien u meer **SFERA GYMNEMA** 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 GYMNEMA** te neem

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

#### 4. MOONTLIKE NEWE EFFEKTE

**SFERA GYMNEMA** kan nuwe effekte hê.

Nie al die nuwe effekte aangemeld vir **SFERA GYMNEMA** is ingesluit in hierdie blaadjie nie. Stel u dokter in kennis as enige van die volgende nuwe effekte voorkom: Nuwe-effekte wat minder gereeld voorkom: Hipoglukemie (lae bloedsuiker). Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar wanneer u **SFERA GYMNEMA** neem. As enige van die volgende gebeur, moet u ophou om **SFERA GYMNEMA** te neem en u dokter onmiddellik inlig van die ongevalle-afdeling in u naaste hospitaal gaan:

- Swelling van die hande, voete, enkels, 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 GYMNEMA** 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](mailto: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 GYMNEMA** voorsien.

#### 5. HOE OM SFERA GYMNEMA 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

**SFERA GYMNEMA** bevat

Elke kapsule bevat:

- *Gymnema Sylvestre* (Gymnema) [blare, uitreksel gestandaardiseer vir 'n minimum van 75% gimneemiese sure]. 300 mg
- Die ander bestanddele is: 'n Vegetariese kapsule, natuurlike vloeï middel en mikrokristallyne sellulose.

#### **SFERA GYMNEMA** lyk en die inhoud van die verpakking

**SFERA GYMNEMA** kapsules is deursigtige grootte "0" kapsules gevul met 'n bruin peule. **SFERA GYMNEMA**: 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

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

#### Hierdie pamflet is laas hersien in

Januarie 2024.

#### Registrasienuommer

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](http://www.sfera-nutrition.co.za)