

PATIENT INFORMATION LEAFLET: SFERA BACOPIN

SCHEDULING STATUS **SO**

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL DOSAGE FORM

SFERA BACOPIN. Each capsule contains: 300 mg *Bacopa monnieri* (Brahmi) [whole herb, extract standardised for a minimum of 20% bacosides].

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

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

What is in this leaflet

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

1. WHAT SFERA BACOPIN IS USED FOR

SFERA BACOPIN helps to support cognitive health and/or brain function.
SFERA BACOPIN may assist with memory enhancement and support.

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

Do not take **SFERA BACOPIN**:

- if you are hypersensitive (allergic) to any of the ingredients of **SFERA BACOPIN** (see section 6).

Warnings and precautions

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

Children and adolescents

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

Other medicines and **SFERA BACOPIN**:

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

SFERA BACOPIN with food and drink:

Take **SFERA BACOPIN** 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 BACOPIN** 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 BACOPIN** affects them.

3. HOW TO TAKE SFERA BACOPIN

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

Always take **SFERA BACOPIN** 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.

If you take more **SFERA BACOPIN** 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 BACOPIN**:

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

4. POSSIBLE SIDE EFFECTS

SFERA BACOPIN can have side effects. Not all side effect reported for **SFERA BACOPIN** are included in this leaflet. The most common side-effects of **SFERA BACOPIN** are gastro-intestinal disturbances. Should your general health worsen or if you experience any untoward effects while taking **SFERA BACOPIN**, please consult your health care provider for advice. If any of the following happens, stop taking **SFERA BACOPIN** 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 BACOPIN**. 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 experience 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 BACOPIN**.

5. HOW TO STORE SFERA BACOPIN

- 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 BACOPIN** contains

- The active substance is: Each capsule contains 300 mg *Bacopa monnieri* (Brahmi) [whole herb, extract standardised for a minimum of 20% bacosides].
- The other ingredients are: A vegetarian capsule and microcrystalline cellulose.

What **SFERA BACOPIN** looks like and contents of the pack

SFERA BACOPIN capsules are clear size "0" capsules filled with a brown powder.
SFERA BACOPIN: 60 capsules are packed into an amber glass bottle, with a golden plastic childproof 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

PASIËNT INLIGTINGSBLAD: SFERA BACOPIN

SKEDULERING STATUS S0

PRODUKNAAM, STERKTE EN DOSEERVORM

SFERA BACOPIN. Elke kapsule bevat 300 mg *Bacopa monnieri* (Brahmi) [hele kruie, ekstrakte gestandaardiseer vir 'n minimum van 20% bacosides].

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

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

Wat is in hierdie blaadjie

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

1. WAT IS SFERA BACOPIN EN WAARVOOR WORD DIT GEBRUIK

SFERA BACOPIN help om kognitiewe gesondheid en/of breinfunksie te ondersteun. **SFERA BACOPIN** kan help met geheueverbetering en ondersteuning van geheue.

2. WAT U MOET WEET VOORDAT U SFERA BACOPIN GEBRUIK

Moenie SFERA BACOPIN neem nie:

- indien u hipersensitief (allergies) is vir enige van die bestanddele van **SFERA BACOPIN** (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.

Kinders en adolessente

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

Ander medisyne en SFERA BACOPIN:

Vertel altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in).

SFERA BACOPIN saam met voedsel en vloeistowwe:

Neem **SFERA BACOPIN** 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 BACOPIN** 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 BACOPIN** hulle beïnvloed.

3. HOE OM SFERA BACOPIN TE GEBRUIK

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

Neem altyd **SFERA BACOPIN** 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: Neem een (1) kapsule oraal daaglik met 'n maaltyd, of soos aangedui deur u gesondheidsorgverskaffer.

Indien u die indruk het dat die effek van **SFERA BACOPIN** te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u meer SFERA BACOPIN 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 BACOPIN te neem:

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

4. MOONTLIKE NEWE EFFEKTE

SFERA BACOPIN kan nuwe effekte hê. Nie alle nuwe-effekte wat vir **SFERA BACOPIN** gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Stel u dokter in kennis as enige van die volgende nuwe effekte voorkom: Die mees algemene nuwe-effekte van **SFERA BACOPIN** is gastro-intestinale versteurings. Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar wanneer u **SFERA BACOPIN** neem. As enige van die volgende gebeur, moet u ophou om **SFERA BACOPIN** 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 BACOPIN** 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 BACOPIN** te voorsien.

5. HOE OM SFERA BACOPIN TE BERG

- Hou alle medisyne buite bereik van kinders.
- Berg by of benede 25 °C.
- Beskerm teen vog.
- Berg in die oorspronklike houertyd 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 rioelstelsels (bv. toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat SFERA BACOPIN bevat

- Die aktiewe bestanddeel is: Elke kapsule bevat 300 mg *Bacopa monnieri* (Brahmi) [hele kruie, ekstrakte gestandaardiseer vir 'n minimum van 20% bacosides].
- Die ander bestanddele is: 'n Vegetariese kapsule en mikrokristallyne sellulose.

Hoe SFERA BACOPIN lyk en die inhoud van die verpakking

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

Houer van Registrasiesertifikaat

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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

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