

PATIENT INFORMATION LEAFLET: SFERA LION'S MANE MUSHROOM EXTRACT

SCHEDULING STATUS **[S0]**

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

SFERA LION'S MANE MUSHROOM EXTRACT. Each capsule contains 450 mg *Hericium erinaceus* (Lion's Mane mushroom) [fruiting body extract 10:1]. Suitable for vegetarians and vegans. No added sugar.

COMPLEMENTARY MEDICINE: WESTERN HERBAL 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 LION'S MANE MUSHROOM EXTRACT is available without a doctor's prescription, for you to use as a health supplement. Nevertheless you still need to use **SFERA LION'S MANE MUSHROOM EXTRACT** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **SFERA LION'S MANE MUSHROOM EXTRACT** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. WHAT SFERA LION'S MANE MUSHROOM EXTRACT IS USED FOR

SFERA LION'S MANE MUSHROOM EXTRACT promotes and maintains overall cognitive health.

SFERA LION'S MANE MUSHROOM EXTRACT is a source of fungal polysaccharides with immunomodulating properties and provides antioxidants which help protect cells against the oxidative effects of free radicals.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SFERA LION'S MANE MUSHROOM EXTRACT

Do not take SFERA LION'S MANE MUSHROOM EXTRACT:

- if you are hypersensitive (allergic) to any of the ingredients of **SFERA LION'S MANE MUSHROOM EXTRACT**.
- if you are hypersensitive (allergic) to mushrooms.
- if you are pregnant or breastfeeding.

Warnings and precautions:

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

Children and adolescents:

Only use under the direct supervision of a health care provider, dosage must be age specific.

Other medicines and SFERA LION'S MANE MUSHROOM EXTRACT:

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

SFERA LION'S MANE MUSHROOM EXTRACT with food and drink:

Take **SFERA LION'S MANE MUSHROOM EXTRACT** 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 LION'S MANE MUSHROOM EXTRACT** 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 LION'S MANE MUSHROOM EXTRACT** affects them.

3. HOW TO TAKE SFERA LION'S MANE MUSHROOM EXTRACT

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

Always take **SFERA LION'S MANE MUSHROOM EXTRACT** 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: Take one (1) to three (3) capsules orally in divided doses during the day, or as directed by your health care provider.

If you take more SFERA LION'S MANE MUSHROOM EXTRACT 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 LION'S MANE MUSHROOM EXTRACT: Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

SFERA LION'S MANE MUSHROOM EXTRACT can have side effects. Gastrointestinal disturbances are the most common side effects. **SFERA LION'S MANE MUSHROOM EXTRACT** may cause skin itching. Should your general health worsen or if you experience any untoward effects while taking **SFERA LION'S MANE MUSHROOM EXTRACT**, please consult your health care provider for advice. If any of the following happens, stop taking **SFERA LION'S MANE MUSHROOM EXTRACT** 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 LION'S MANE MUSHROOM EXTRACT**. 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 SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index#B>. By reporting side effects, you can help provide more information on the safety of **SFERA LION'S MANE MUSHROOM EXTRACT**.

5. HOW TO STORE SFERA LION'S MANE MUSHROOM EXTRACT

- 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 LION'S MANE MUSHROOM EXTRACT contains

- The active substance is: Each capsule contains 450 mg *Hericium erinaceus* (Lion's Mane mushroom) [fruiting body extract 10:1].
- The other ingredient is: A vegetarian capsule and microcrystalline cellulose.

What SFERA LION'S MANE MUSHROOM EXTRACT looks like and contents of the pack

SFERA LION'S MANE MUSHROOM EXTRACT capsules are clear size "0" capsules filled with a brown powder.

SFERA LION'S MANE MUSHROOM EXTRACT: 60 & 180 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 LION'S MANE MUSHROOM EXTRACT

SKEDULERING STATUS S0

PRODUKNAAM, STERKTE EN DOSEERVORM

SFERA LION'S MANE MUSHROOM EXTRACT. Elke kapsule bevat 450 mg *Hericium erinaceus* (Lion's Mane sampioen) [vrug deel ekstrak 10:1].

Geskik vir vegetaniërs en vegane.

Geen Suiker bygevoeg.

KOMPLEMENTÊRE MEDISYNE: WESTERSE KRUIE MEDISYNE

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

- Hou hierdie blaadjie. U mag dit weer wil lees.
- Moenie **SFERA LION'S MANE MUSHROOM EXTRACT** deel met enige ander persoon nie.
- Vra u gesondheidsorgverskaffer of apteaker indien u meer inligting of advies benodig.

Wat is in hierdie blaadjie

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

1. WAT IS SFERA LION'S MANE MUSHROOM EXTRACT EN WAARVOOR WORD DIT GEBRUIK

SFERA LION'S MANE MUSHROOM EXTRACT bevorder en handhaaf algehele kognitiewe gesondheid.

SFERA LION'S MANE MUSHROOM EXTRACT is 'n bron van swam polisakkariede met immuun-modulerende eienskappe en verskaf anti-oksidante wat selle beskerm teen die oksidatiewe effekte van vrye radikale.

2. WAT U MOET WET VOORDAT U SFERA LION'S MANE MUSHROOM EXTRACT GEBRUIK

Moenie **SFERA LION'S MANE MUSHROOM EXTRACT** neem nie:

- indien u hipersensitief (allergies) is vir enige van die bestanddele van **SFERA LION'S MANE MUSHROOM EXTRACT**.
- Indien u hipersensitief (allergies) is vir sampioene.
- indien u swanger is of u baba borsvoed.

Waarskuwings en voorsorgmaatreëls:

Raadpleeg u dokter voordat u **SFERA LION'S MANE MUSHROOM EXTRACT** begin gebruik, veral as u 'n mediese toestand het of voorskryfmedisyne gebruik.

Kinders en adolessente:

Gebruik slegs onder die direkte toesig van 'n gesondheidsorgverskaffer, dosering is ouderdom spesifiek.

Ander medisyne en SFERA LION'S MANE MUSHROOM EXTRACT:

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

SFERA LION'S MANE MUSHROOM EXTRACT saam met voedsel en vloeistowwe: Neem **SFERA LION'S MANE MUSHROOM EXTRACT** 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, apteaker 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 LION'S MANE MUSHROOM EXTRACT** 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 LION'S MANE MUSHROOM EXTRACT** hulle beïnvloed.

3. HOE OM SFERA LION'S MANE MUSHROOM EXTRACT TE GEBRUIK

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

Neem altyd **SFERA LION'S MANE MUSHROOM EXTRACT** presies soos voorgeskryf in hierdie pamflet of soos u dokter, apteaker of gesondheidsorgverskaffer vir u gesê het. Raadpleeg u dokter, apteaker of gesondheidsorgverskaffer as u nie seker is nie. Die gewone dosis is: Neem een (1) tot drie (3) kapsules oraal per dag na ete, of soos aangedui deur u gesondheidsorgverskaffer.

Indien u meer SFERA LION'S MANE MUSHROOM EXTRACT neem as wat u behoort te neem:

In die geval van 'n oordosis, raadpleeg u dokter of apteaker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gif hulp sentrum.

Indien u vergeet om 'n dosis SFERA LION'S MANE MUSHROOM EXTRACT te neem:

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

4. MOONTLIKE NEWE EFFEKTE

SFERA LION'S MANE MUSHROOM EXTRACT kan newe effekte hê. Gastro-intestinale steurings is die algemeenste newe effekte. **SFERA LION'S MANE MUSHROOM EXTRACT** kan jouk van die vel veroorsaak. Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar wanneer u **SFERA LION'S MANE MUSHROOM EXTRACT** neem. As enige van die volgende gebeure, moet u ophou om **SFERA LION'S MANE MUSHROOM EXTRACT** 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.
- Flou word.

Dit is alles baie ernstige newe-effekte. As u dit het, kan u 'n ernstige reaksie op **SFERA LION'S MANE MUSHROOM EXTRACT** gehad het. U mag dringend mediese hulp of hospitalisasie benodig. Stel u dokter of apteaker 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 apteaker praat. U kan ook newe-effekte aan 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 LION'S MANE MUSHROOM EXTRACT** voorsien.

5. HOE OM SFERA LION'S MANE MUSHROOM EXTRACT 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 apteaker toe.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat **SFERA LION'S MANE MUSHROOM EXTRACT** bevat

- Die aktiewe bestanddele is: Elke kapsule bevat 450 mg *Hericium erinaceus* (Lion's Mane mushroom) [vrug deel ekstrak 10:1].
- Die ander bestanddele is: 'n Vegetariese kapsule en mikrokristallyne sellulose.

Hoe **SFERA LION'S MANE MUSHROOM EXTRACT** lyk en die inhoud van die verpakking **SFERA LION'S MANE MUSHROOM EXTRACT** kapsules is deursigtige kapsules gevul met 'n bruin poeier.

SFERA LION'S MANE MUSHROOM EXTRACT: 60 & 180 kapsules word verpak in 'n amber glasbottel, met 'n goudkleurige peuter bestande deksel met 'n druk-seël voering, silika gel sakkie en 'n beskermende selluloos 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

Hierdie pamflet is laas hersien in

Januarie 2024.

Registrasie nommer

Sal gealokeer word deur SAHPRA deur 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