

**PATIENT INFORMATION LEAFLET**
**SCHEDULING STATUS:**  S0

**PRODUCT NAME**

BIOGEN LION'S MANE EXTRACT

**D. 33.4. Complementary Medicine: Traditional Chinese Medicine**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

**Read all of this leaflet carefully because it contains important information for you.** BIOGEN LION'S MANE EXTRACT is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN LION'S MANE EXTRACT carefully to get the best results from it.

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

**What is in this leaflet**

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

**1. What BIOGEN LION'S MANE EXTRACT is and what it is used for**  
 BIOGEN LION'S MANE EXTRACT is a source of fungal polysaccharides with immunomodulating properties and provides antioxidants.

**2. What you need to know before you take BIOGEN LION'S MANE EXTRACT**  
**Do not take BIOGEN LION'S MANE EXTRACT:**

- If you are hypersensitive (allergic) to any of the ingredients of BIOGEN LION'S MANE EXTRACT (listed in section 6).
- Avoid use if you are pregnant or breastfeeding.

**Warnings and precautions**

Special care should be taken with BIOGEN LION'S MANE EXTRACT. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- If you are scheduled for an elective surgical procedure. You should stop taking BIOGEN LION'S MANE EXTRACT at least 2 weeks before any elective surgical procedures.
- Consult a relevant healthcare provider prior use if you are pregnant or breastfeeding.
- Consult a relevant healthcare provider prior use if you if you are taking blood thinners (anti-coagulants).

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

**Children and adolescents**

BIOGEN LION'S MANE EXTRACT is not recommended for individuals below the age of 18 years.

**Other medicines and BIOGEN LION'S MANE EXTRACT**

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine.

The following medicines may cause an interaction with BIOGEN LION'S MANE EXTRACT:

- *Heridium Erinaceus* might have antiplatelet effects and increase the risk of bruising or bleeding in patients with bleeding disorders.
- *Heridium Erinaceus* might have hypoglycemic effects.
- *Heridium Erinaceus* may have additive effects when used with antidiabetic medication.

**BIOGEN LION'S MANE EXTRACT with food and drink**

BIOGEN LION'S MANE EXTRACT has no known interaction with food and drink (see section 3).

**Pregnancy, breastfeeding and fertility**

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 healthcare provider for advice before using BIOGEN LION'S MANE EXTRACT.

Safety for use during pregnancy and lactation has not been established.

**Driving and using machinery**

BIOGEN LION'S MANE EXTRACT is unlikely to influence your ability to drive a vehicle and operate machinery. Patients should exercise caution before driving or using machinery until they are reasonably certain that BIOGEN LION'S MANE EXTRACT does not adversely affect their performance.

**3. How to take BIOGEN LION'S MANE EXTRACT**

Always use BIOGEN LION'S MANE EXTRACT exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

*Adults 18 years and older*

Take 1 (one) vegetable capsule daily with meals, or as recommended by a healthcare provider. Do not exceed the recommended dose.

**If you take more BIOGEN LION'S MANE EXTRACT than you should**

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining capsules with you so the doctor will know what you have taken.

**If you forget to take BIOGEN LION'S MANE EXTRACT**

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

**4. Possible side effects**

BIOGEN LION'S MANE EXTRACT can have side effects.

Not all side effects reported for BIOGEN LION'S MANE EXTRACT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN LION'S MANE EXTRACT, please consult your healthcare provider for advice.

If any of the following happens, stop using BIOGEN LION'S MANE EXTRACT and tell your doctor immediately, or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and 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 BIOGEN LION'S MANE EXTRACT. You may need urgent medical attention or hospitalisation.

Tell your doctor as soon as possible if you notice any of the following:

- Gastrointestinal discomfort and nausea
- Skin rash

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 Adverse Drug Reactions Reporting Form, found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIOGEN LION'S MANE EXTRACT.

**5. How to store BIOGEN LION'S MANE EXTRACT**

- Store at or below 25 °C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

**6. Contents of the pack and other information**
**What BIOGEN LION'S MANE EXTRACT contains**

Each vegetable capsule contains:

*Heridium Erinaceus* (Lion's Mane Mushroom) 2 000,00 mg  
 [Fruiting body; as 250 mg of a 10:1 extract]

The other ingredients are magnesium stearate, potato starch and silicon dioxide. Sugar free.

**7. What BIOGEN LION'S MANE EXTRACT looks like and contents of the pack**

Size 0 white / white vegetable capsules packed in a 175 ml White PET container with a Biogen cap.

Pack size: 30 Vegetable Capsules

**8. Holder of certificate of registration**

 Biogen  
 23 Stag Road,  
 Glen Austin,  
 South Africa  
 info@biogen.co.za  
 www.biogen.co.za  
 Tel: 0860 347243

**9. This leaflet was last revised in**

Will be allocated by SAHPRA upon registration.

**10. Registration Number**

 Will be allocated by SAHPRA upon registration.  
 See www.biogen.co.za for professional information.

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|---|---|---|---|
| <b>JOB:</b> BPS_Lions_Mane_Mushroom_30s   |   | <b>SIZE:</b> 148mm x 210mm              |   |
| <b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/> |   |   |   |
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**PASIËNTINLIGTINGSBLAD** 
 **SKEDULERINGSSTATUS:**  S0

 **PRODUK NAAM** 

BIOGEN LION'S MANE EXTRACT

 **D. 33.4. Komplementêre Medisyne: Tradisionele Chinese Medisyne** 

Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

 **Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir u.** 

BIOGEN LION'S MANE EXTRACT is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN LION'S MANE EXTRACT nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN LION'S MANE EXTRACT met enigiemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of apteker indien u verdere inligting of advies nodig het.

 **Wat is in hierdie inligtingsblad** 

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

 **1. Wat is BIOGEN LION'S MANE EXTRACT en waarvoor word dit gebruik** 

BIOGEN LION'S MANE EXTRACT, n bron van swam polisakkariëde met immunomodulerende eienskappe en verskaf antioksidante.

 **2. Wat u moet weet voordat u BIOGEN LION'S MANE EXTRACT neem** 
 **Moenie BIOGEN LION'S MANE EXTRACT neem nie:** 

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele van BIOGEN LION'S MANE EXTRACT (gelys in afdeling 6).
- Vermoed gebruik indien u swanger is of borsvoed.

 **Waarskuwings en voorsorgmaatreëls** 

Spesiale sorg moet toegepas word met die gebruik van BIOGEN LION'S MANE EXTRACT. Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik.

Let asselief op die volgende:

- As jy geskeduleer is vir 'n elektiewe chirurgiese prosedure. Jy moet ten minste 2 weke voor enige elektiewe chirurgiese prosedures ophou om BIOGEN LION'S MANE EXTRACT te neem.
- Raadpleeg 'n relevante gesondheidsorgverskaffer voor gebruik as jy swanger is of borsvoed.
- Raadpleeg 'n relevante gesondheidsorgverskaffer voor gebruik as u bloedverduiners (anti-stollingsmiddels) gebruik.

Voedingsaanvullings moet nie 'n gebalanseerde dieet vervang nie. Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

 **Kinders en adolessente** 

BIOGEN LION'S MANE EXTRACT word nie aanbeveel vir individue onder die ouderdom van 18 jaar nie.

 **Ander medisyne en BIOGEN LION'S MANE EXTRACT** 

Lig altyd jou gesondheidsorgverskaffer in indien jy enige ander medisyne neem. Dit sluit aanvallende of tradisionele medisyne in.

Die volgende medisyne kan interaksie met BIOGEN LION'S MANE EXTRACT hê:

- *Hericium Erinaceus* kan *teenplaattie-effekte hê en die risiko van kneusing of bloeding verhoog by pasiënte met bloedingsversteurings.*
- *Hericium Erinaceus* kan *hipoglisemiese-effekte hê.*
- *Hericium Erinaceus* kan *bykomende effekte hê wanneer dit saam met anti-diabetiese medikasie gebruik word.*

 **BIOGEN LION'S MANE EXTRACT met kos en drinkgoed** 

BIOGEN LION'S MANE EXTRACT het geen bekende interaksies met kos of drinkgoed nie (sien afdeling 3).

 **Swangerskap, borsvoeding en vrugbaarheid** 

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asselief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy BIOGEN LION'S MANE EXTRACT neem.

Veiligheid vir gebruik tydens swangerskap en laktasie is nie vasgestel nie.

 **Bestuur en die gebruik van masjinerie** 

Dit is onwaarskynlik dat BIOGEN LION'S MANE EXTRACT jou vermoë om 'n voertuig te bestuur en masjinerie te gebruik sal affekteer. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat BIOGEN LION'S MANE EXTRACT nie hul werkverrigting nadelig beïnvloed nie.

 **3. Hoe om BIOGEN LION'S MANE EXTRACT te neem** 

Gebruik BIOGEN LION'S MANE EXTRACT altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker vir jou aangewys het. Vra gerus jou dokter of apteker indien jy onseker is.

 **Volwassenes 18 jaar en ouer** 

Neem 1 (een) groentekapsule daagliks saam etes, of soos aanbeveel deur jou gesondheidsorgverskaffer. Moenie die aanbevole dosis oorskry nie.

 **Wat om te doen indien u meer BIOGEN LION'S MANE EXTRACT geneem het as wat u moet** 

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en die res van die kapsules saam sodat die dokter weet wat jy geneem het.

 **Indien u vergeet om BIOGEN LION'S MANE EXTRACT te neem** 

Moenie 'n dubbele dosis neem om op te maak vir die individuele dosisse wat oorgeslaan is nie.

 **4. Moontlike newe-effekte** 

BIOGEN LION'S MANE EXTRACT kan newe-effekte hê.

Nie alle newe-effekte wat vir BIOGEN LION'S MANE EXTRACT gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid swak of indien jy enige ongunstige effekte ervaar onderwyl jy BIOGEN LION'S MANE EXTRACT geneem word, raadpleeg asselief jou gesondheidsverskaffer.

Indien jy enige van die volgende ervaar, hou op om BIOGEN LION'S MANE EXTRACT te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jouse naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- Uitslag of gejeuk;
- Floute.

Hierdie is baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op BIOGEN LION'S MANE EXTRACT gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê so gou as moontlik vir jou dokter indien jy enige van die volgende opmerk:

- Gastroïntestinale ongemak en naardeid
- Veluitslag

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

 **Rapportering van newe-effekte** 

 Indien u newe-effekte ondervind, bespreek dit met u dokter of apteker. U kan ook newe-effekte aan SAHPRA rapporteer via die Adverse Drug Reactions Reporting Form, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.

Deur newe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN LION'S MANE EXTRACT te verskaf.

 **5. Hoe om BIOGEN LION'S MANE EXTRACT te bêre** 

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

 **6. Inhoud van die pak en ander inligting** 
 **Wat BIOGEN LION'S MANE EXTRACT bevat** 

Elke groentekapsule bevat:

*Hericium Erinaceus* (Lion's Mane Sampioen) 2 000,00 mg  
 [Vrugliggaam: as 200 mg van 'n 10: 1 ekstras]

Die ander bestanddele is mieliestysel, silikondioksied en magnesiumstearaat. Suikervry.

 **7. Hoe BIOGEN LION'S MANE EXTRACT lyk en inhoud van die verpakking** 

Grootte 0 wit / wit groentekapsules verpak in 'n 175 ml Wit PET houer met 'n Biogen deksel.

Verpakkingsgrootte: 30 Groentekapsules.

 **8. Houer van die registrasiesertifikaat** 

 Biogen  
 23 Stag Road, Glen Austin, South Africa  
 info@biogen.co.za  
 www.biogen.co.za  
 Tel: 0860 347243

 **9. Hierdie inligtingsblad is laas hersien in** 

Sal met registrasie deur SAHPRA toegeken word.

 **10. Registrasienommer** 

 Sal met registrasie deur SAHPRA toegeken word. Raadpleeg [www.biogen.co.za](http://www.biogen.co.za) vir professionele inligting.

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|   |   | <input type="checkbox"/> Foil / Holographic Foil | <input type="checkbox"/> Matte <input type="checkbox"/> Gloss      |
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