

PROFESSIONAL INFORMATION**D 33.6 Complementary medicine. Western Herbal Medicine**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0**1. NAME OF THE MEDICINE**

BIOGEN TONGKAT ALI

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Eurycoma longifolia Jack (Tongkat Ali)
[Root, 200:1 extract providing 80 g DHE]

Per capsule:

400,00 mg

Sugar Free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bovine gelatine capsules

White to off white powder in a size 0 vegetable capsule.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

BIOGEN TONGKAT ALI, may increase testosterone levels & when combined with strength training may increase muscle mass, endurance, improve athletic performance, recovery & an increase in lean body mass.

4.2 Posology and method of administration*Adults 18 years and older:*

Take 1 (one) capsule daily with meals, or as recommended by your healthcare provider. Use continuously for 4 weeks followed by a 2 week break.

*Elderly:*Considering that *Eurycoma longifolia* extract increases the serum testosterone concentrations, there might be a potential risk from its treatment in elderly men, which might cause prostatic problems.*Patient with impaired renal and/or liver function:*

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

Children and adolescents:

Not recommended in children and adolescents below the age of 18 years (see section 4.4).

4.3 Contraindications

- If you have a hypersensitivity to *Eurycoma longifolia* extract (Tongkat Ali), or any of the excipients listed in 6.1.
- Contraindicated in patients with prostate cancer.
- Contraindicated in patients using hypoglycemic agents

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN TONGKAT ALI.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not recommended for use in children under the age of 18 years.
- Consult a healthcare provider if symptoms persist or worsen.
- Consult a healthcare provider prior to use if you have prostate cancer or a history of prostate cancer.
- Consult a healthcare provider prior to use if you have a compromised immune system, *Eurycoma longifolia* may further weaken the immune function.
- Avoid use in patients with diseases like breast cancer, heart disease, liver disease or sleep apnea.

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

4.5 Interaction with other medicines and other forms of interaction

No specific drug interaction studies have been performed on BIOGEN TONGKAT ALI, however, the pharmacokinetic properties of *Eurycoma longifolia* (Tongkat Ali) have been summarized.

Interactions with Medicines

- *Eurycoma longifolia* (Tongkat Ali) can reduce the levels and clinical effects of propranolol and patients are advised to discuss an appropriate dosing schedule with their healthcare provider.

Interactions with Diseases/Impairments

- *Eurycoma longifolia* (Tongkat Ali) might reduce blood glucose levels. Combined use might increase the risk for hypoglycemia, especially in patients on insulin or oral hypoglycemic medications. Dose adjustments for diabetes medications may be necessary.
- Patients are advised to discontinue BIOGEN TONGKAT ALI at least 2 weeks before elective surgical procedures (see section 4.4).

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN TONGKAT ALI.

Fertility, pregnancy and lactation

The safety and efficacy of BIOGEN TONGKAT ALI in pregnancy and lactation has not been established.

4.6 Effects on ability to drive and use machines

Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN TONGKAT ALI does not affect their performance

4.7 Undesirable effectsOrally, *Eurycoma longifolia* (Tongkat Ali) is well-tolerated.**Summary of adverse reactions**

Gastrointestinal disorders:

Frequency unknown: *Eurycoma longifolia* (Tongkat Ali) can cause abdominal pain, cramping and nausea.

Nervous system disorders:

Frequency unknown: *Eurycoma longifolia* (Tongkat Ali) may cause restlessness, irritability and insomnia.

Endocrine:

Frequency unknown: Tongkat Ali might increase testosterone levels, if testosterone levels are increased beyond the normal range, there is risk of testosterone-related side effects which could include acne, insulin resistance, hepatotoxicity, and others.**Description of selected adverse reactions**

BIOGEN TONGKAT ALI may cause several adverse reactions, such as, gastrointestinal disturbances, such as, abdominal pain.

Paediatric Population

BIOGEN TONGKAT ALI is not recommended for use by children under 18 years, as insufficient data are available concerning its safety and efficacy.

Other special populations

No clinical data are available on the effects of BIOGEN TONGKAT ALI on other special populations.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.8 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES**Mechanism of action:**

The peptides are thought to activate 17-alpha-hydroxylase / 17,20-lyase, resulting in increased metabolism of pregnenolone and 17-OH-pregnenolone to dehydroepiandrosterone (DHEA) and metabolism of progesterone and 17-OH-progesterone to 4-androstenedione and testosterone. Increases muscular strength.

Pharmacodynamic effects:

Specific polypeptides called euryopeptides, have aphrodisiac effects by increasing the body's synthesis of androgens, including testosterone.

Pharmacokinetic properties

Absorption:

The constituents eurycomanone and 9-methoxycanthin-6-one have low bioavailability, rates are 10% and <1%, respectively. The low bioavailability of eurycomanone might be due to low membrane permeability or high first pass metabolism. The constituent 13-alpha-21-epoxyeurycomanone appears to be more bioavailable than eurycomanone following oral intake of *Eurycoma longifolia* extract.

No clinical data are available on the effects of BIOGEN TONGKAT ALI.

Distribution/ Metabolism/ Excretion:

There is insufficient reliable information available about the metabolism of tribulus.

Preclinical safety data

No clinical data are available on the safety of BIOGEN TONGKAT ALI.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Magnesium stearate and silicon dioxide.

6.2 Shelf Life

24 Months.

6.3 Special precautions for storage

Store in a cool, dry place at or below 25 °C. Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.4 Nature and contents of container

30 capsules

The container is a 175 mL PET container. The cap is a plastic cap with a tamper evident seal.

6.5 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen,

23 Stag Rd,

Glen Austin,

South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

July 2022

JOB: BPS_TongkatAli_30s

SIZE: 210mm x 403mm

STOCK: Foil Substrate: Clear Substrate: White Substrate: Paper: Other: **COLOURS:** K Available Slot Available Slot Available Slot Available Slot**FINISHING:** Foil / Holographic Foil Matte Gloss Spot UV Doming Embossing

PLEASE CHECK CAREFULLY

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

PATIENT INFORMATION LEAFLETSCHEDULING STATUS: **SO****PRODUCT NAME****BIOGEN TONGKAT ALI**

Each capsule contains:

Eurycoma longifolia Jack (Tongkat ali) 400 mg

Sugar Free

D 33.6 Complementary medicine, Western Herbal 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 TONGKAT ALI is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN TONGKAT ALI carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN TONGKAT ALI 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 TONGKAT ALI is and what it is used for.
2. What you need to know before you take BIOGEN TONGKAT ALI.
3. How to take BIOGEN TONGKAT ALI.
4. Possible side effects.
5. How to store BIOGEN TONGKAT ALI.
6. Contents of the pack and other information.

1. WHAT BIOGEN TONGKAT ALI IS AND WHAT IT IS USED FOR

BIOGEN TONGKAT ALI may increase testosterone levels & when combined with strength training may increase muscle mass, endurance, improve athletic performance, recovery & an increase in lean body mass.

What you need to know before you take BIOGEN TONGKAT ALI**Do not take BIOGEN TONGKAT ALI:**

- If you have a hypersensitivity (Allergy) to *Eurycoma longifolia* extract (Tongkat Ali) or any of the excipients listed in 6.1.
- Not advised in patients with prostate cancer.
- Not advised in patients using hypoglycemic agents

Warnings and precautions

Special care should be taken with BIOGEN TONGKAT ALI.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not recommended for use in children under the age of 18 years.
- Consult a healthcare provider if symptoms persist or worsen.
- Consult a healthcare provider prior to use if you have prostate cancer or a history of prostate cancer.
- Consult a healthcare provider prior to use if you have a compromised immune system, *Eurycoma longifolia* may further weaken the immune function.
- Avoid use in patients with diseases like breast cancer, heart disease, liver disease or sleep apnea.

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

Children and adolescents

BIOGEN TONGKAT ALI is not recommended for use in children under the age of 18 years.

Other medicines and BIOGEN TONGKAT ALI

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine. It is advised to consult your doctor if you want to take BIOGEN TONGKAT ALI combined with other medicines or treatments such as:

- *Eurycoma longifolia* (Tongkat Ali) can reduce the levels and clinical effects of propranolol and patients are advised to discuss an appropriate dosing schedule with their healthcare provider.

Interactions with Diseases / Impairments

- *Eurycoma longifolia* (Tongkat Ali) might reduce blood glucose levels. Combined use might increase the risk for hypoglycemia, especially in patients on insulin or oral hypoglycemic medications. Dose adjustments for diabetes medications may be necessary.
- Patients are advised to discontinue BIOGEN TONGKAT ALI at least 2 weeks before elective surgical procedures (see section 4).

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN TONGKAT ALI.

Pregnancy, breastfeeding and fertility

The safety and efficacy of BIOGEN TONGKAT ALI in pregnancy and lactation has not been established.

Driving and using machinery

Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN TONGKAT ALI does not affect their performance.

2. HOW TO TAKE BIOGEN TONGKAT ALI

Do not share your medicines with any other person.

Always take BIOGEN TONGKAT ALI 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) capsule daily with meals, or as recommended by your healthcare provider. Use continuously for 4 weeks followed by a 2 week break.

Elderly: Considering that *Eurycoma longifolia* extract increases the serum testosterone concentrations, there might be a potential risk from its treatment in elderly men, which might cause prostatic problems.

Patient with impaired renal and/or liver function: In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4).

Children and adolescents: The safety and efficacy of BIOGEN TONGKAT ALI in children has not yet been established. Not allowed in children under 18 years.

If you take more BIOGEN TONGKAT ALI than you should

No known information. In the event of an over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN TONGKAT ALI with you so the doctor will know what you have taken.

If you forget to take BIOGEN TONGKAT ALI

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

3. POSSIBLE SIDE EFFECTS

BIOGEN TONGKAT ALI can have side effects.

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

Side effects associated;**Gastrointestinal disorders:**
Frequency unknown: *Eurycoma longifolia* (Tongkat Ali) can cause abdominal pain, cramping and nausea.**Nervous system disorders:**
Frequency unknown: *Eurycoma longifolia* (Tongkat Ali) may cause restlessness, irritability and insomnia.**Endocrine:***Frequency unknown:* Tongkat Ali might increase testosterone levels, if testosterone levels are increased beyond the normal range, there is risk of testosterone-related side effects which could include acne, insulin resistance, hepatotoxicity, and others.

Should your general health worsen or if you experience any untoward effects while BIOGEN TONGKAT ALI, please consult your doctor, pharmacist or other healthcare practitioner for advice.

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

Reporting of side effectsIf 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 TONGKAT ALI.

4. HOW TO STORE BIOGEN TONGKAT ALI

- 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).

5. CONTENTS OF THE PACK AND OTHER INFORMATION WHAT BIOGEN TONGKAT ALI CONTAINS**What BIOGEN TONGKAT ALI contains***Eurycoma longifolia* (Tongkat Ali) 400,00 mg

Sugar Free

The other ingredients are Magnesium stearate and Silicon dioxide

6. WHAT BIOGEN TONGKAT ALI LOOKS LIKE AND CONTENTS OF THE PACK

30 Capsules

The container is a 175 mL PET container, with a Biogen embossed cap and a tamper evident seal.

7. HOLDER OF CERTIFICATE OF REGISTRATIONBiogen,
23 Stag Rd,
Glen Austin,
South Africa**8. THIS LEAFLET WAS LAST REVISED IN**

July 2022

9. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLADSKEDULERINGSTATUS: **SO****BIOGEN TONGKAT ALI**

Elke kapsule bevat:

Eurycoma longifolia Jack (Tongkat ali) 400 mg

Suikervry.

D 33.6 Komplementêre Medisyne. Westerse Krui Medisyne

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

Lees hierdie hele inligtingsblad aandagdig deur want dit bevat inligting wat belangrik is vir u.
BIOGEN TONGKAT ALI is beskikbaar sonder 'n dokter se voorskrif, sodat u gesondheid kan onderhou. U moet BIOGEN TONGKAT ALI niemendien steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN TONGKAT ALI met enigemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of apteker indien u verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

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

1. WAT IS BIOGEN TONGKAT ALI EN WAARVOOR WORD DIT GEBRUIK

BIOGEN TONGKAT ALI kan testosteroonvlakte verhoog en wanneer dit gekombineer word met kragoefening, kan dit lei tot verhoogde spiermassa, uitluwermoë, verbeterde atletiese prestasie, herstel en toename in maer liggaamsmassa.

Wat u moet weet voordat u BIOGEN TONGKAT ALI neem nie

Moenie BIOGEN TONGKAT ALI neem nie:

- As jy 'n hipersensitiviteit (Allergie) het *Eurycoma longifolia* (Tongkat ali), of enige van die hulpstowwe gelys in 6.1.
- Teenaangedui by pasiënt met prostaatkanker.
- Teenaangedui by pasiënt wat gebruik maak van hipoglisemiese middels

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet toegepas word met die gebruik van BIOGEN TONGKAT ALI.

Raadpleeg u gesondheidspraktisyen voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik. Let asseblief op die volgende:

- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy swanger is of borsvoed.
- Nie aanbeveel vir gebruik by kinders onder die ouderdom van 18 jaar nie.
- Raadpleeg 'n gesondheidsorgverskaffer indien simptome voortduur van vererger.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy prostaatkanker of 'n geskiedenis van prostaatkanker het.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy 'n gekompromitteerde immuunstelsel het, *Eurycoma longifolia* kan die immuunfunksie verder verswak.
- Vermy gebruik by pasiënte met siektes soos borskanker, hartsiektes, lewersiekte of slaapapnee

Kinders en adolescentes

BIOGEN TONGKAT ALI word nie vir kinders onder die ouderdom van 18 jaar aanbeveel nie.

Ander medisyne en BIOGEN TONGKAT ALI

Lig altyd u gesondheidspraktisyen in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN TONGKAT ALI wil combineer saam met ander medisyne of behandeling soos:

- *Eurycoma longifolia* (Tongkat Ali) kan die vlakte en kliniese effekte van propranolol verminder en pasiënte word aangeraai om 'n toepaslike doseringskedisie met hul gesondheidsorgverskaffer te bespreek.

Interaksies met siektes / gestremdhede

- *Eurycoma longifolia* (Tongkat Ali) kan bloedglukosevlakte verlaag. Gekombineerde gebruik kan die risiko vir hipoglukemie verhoog, veral by pasiënte wat insuline of orale hipoglisemiese medisyne gebruik. Dosisaanpassings vir diabètesmediske kan nodig wees.
- Pasiënte word aangeraai om BIOGEN TONGKAT ALI ten minste 2 weke voor elektiewe chirurgiese prosedures te staak (sien afdeling 4).

Interaksies met voedsel

- Vitamiene, minerale en voedingstowwe wat van ander bronne verkry word, moet in ag geneem word wanneer BIOGEN TONGKAT ALI voorgeskreif / voorgestel word.

Swangerskap, borsvoeding en vrugbaarheid

Die veiligheid en doeltreffendheid van BIOGEN TONGKAT ALI tydens swangerskap en laktasie is nie vasgestel nie.

2. HOE OM BIOGEN TONGKAT ALI TE NEEM

Moenie u medisyne met enigemand anders deel nie.

Neem, BIOGEN TONGKAT ALI altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat u dokter of apteker vir u aanbeveel het. Vra gerus u dokter of apteker indien u onseker is.

Volvassenes 18 jaar en ouer: Neem daagliks 1 (een) kapsule saam met etes, of soos aanbeveel deur jou gesondheidsorgverskaffer. Gebruik deurlopend vir 4 weke gevvolg deur 'n 2 weke break.

Bejaardes: Aangesien *Eurycoma longifolia* uittreksel die serum testosteronkonkentrasiës verhoog, kan daar 'n potensiële risiko wees van die behandeling daarvan by bejaarde mans, wat prostaatprobleme kan veroorsaak.

Pasiënt met verswakte nier- en/of leverfunksie: By pasiënte met verswakte nier- en/of leverfunksie kan geen dosisaanbevelings gegee word nie, aangesien geen studies uitgevoer is nie (sien ook afdeling 4).

Kinders en adolescentes: Word nie aanbeveel by kinders en adolescentes onder die ouderdom van 18 jaar nie (sien afdeling 4).

Die veiligheid en doeltreffendheid van BIOGEN TONGKAT ALI by kinders is nog nie vasgestel nie. Nie toegelaat by kinders onder 18 jaar nie.

Wat om te doen indien u meer BIOGEN TONGKAT ALI geneem het as wat u moet

Geen bekende informasie. Indien u meer BIOGEN TONGKAT ALI geneem het as wat u moes, of in die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende BIOGEN TONGKAT ALIolie saam sodat die dokter kan sien wat u ingeneem het.

Indien u vergeet om BIOGEN TONGKAT ALI te neem

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

3. MOONLIKE NEWE-EFFEKTE

BIOGEN TONGKAT ALI kan newe-effekte hê.

Nie alle newe-effekte wat aangedui is vir BIOGEN TONGKAT ALI is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongew