

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: Per capsule:
Eurycoma longifolia Jack (Tongkat Ali) 400,00 mg
 [Root, 200:1 extract providing 80 g DHE]

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 effects

Orally, *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 euryptides, 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: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Foil / Holographic Foil		<input type="checkbox"/> Matte <input type="checkbox"/> Gloss	
<input type="checkbox"/> Spot UV		<input type="checkbox"/> Dornung <input type="checkbox"/> 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.			

