

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S0

### FEMALE HEALTH SUPPORT TONIC

CATEGORY D COMPLEMENTARY MEDICINE

DISCIPLINE: Discipline Specific Traditional 33.6 – Western Herbal Medicine

This unregistered medicine has not been evaluated by the South African Health Product Regulatory Authority for its safety, quality or intended use.

#### Read all of this leaflet carefully because it contains important information for you

- **Tonkat Ali Tonic** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **Tonkat Ali Tonic** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **Tonkat Ali Tonic** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

#### What is in this leaflet

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

#### 1 What Tonkat Ali Tonic is and what it is used for:

Each dose (15 drops) provides:

Eurycoma longifolia (Tonkat Ali root 10:1 extract)

Ethanol 62%

%NRV

\*

\*

Nutrient Reference Values (NRVs) for individuals 4 years and older

\*%NRV not established

Sugar free

Tonkat Ali Tonic is indicated as a general supplement where a deficiency of any of the ingredients exists.

#### 2 What you need to know before you take/ use Tonkat Ali Tonic:

Do not take **Tonkat Ali Tonic** if you are hypersensitive (allergic) to any of the ingredients.

#### Warnings and precautions:

Discontinue the use of this product where there is sensitivity towards any of the ingredients.

#### Other medicines and Tonkat Ali Tonic:

If you are using chronic prescription medication, use it under the supervision of your healthcare practitioner. If you are taking any concomitant immunosuppressants you should only consider taking this supplement after consultation with your doctor, and do so under strict medical supervision. Discontinue use at least 2 weeks prior to undergoing planned surgical procedures.

#### Take special care:

If you suffer from a chronic medical condition, only use the supervision of your healthcare practitioner. If you suffer from prostate cancer, male breast cancer, diabetes mellitus, heart disease, sleep apnea or any liver or kidney diseases tonic should only be used under the supervision of a health care practitioner.

#### Pregnancy and breastfeeding and fertility:

Pregnant and breastfeeding women should avoid using this product.

#### Driving and using machinery:

It is not always possible to predict to what extent **Tonkat Ali Tonic** 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 **Tonkat Ali Tonic** affects them.

#### 3 How to take /use Tonkat Ali Tonic.

Adults: 10 to 15 drops, under the tongue, 2 times a day.

Children under the age of 16 years: 1 drop per age of the child, under the tongue, 2 times a day.

Keep under the tongue for 1 minute. Take with a little water if too strong to keep under the tongue

Do not exceed the recommended dose.  
For oral use.

**If you take more than you should:**

When taken at appropriate doses, generally considered safe. Side effects tend to be dose-related.

**4 Possible side effects:**

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

**If any of the following happens, stop taking and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- difficulty breathing

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **Tonkat Ali Tonic**. You may need urgent medical attention or hospitalisation.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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/8>. By reporting side effects, you can help provide more information on the safety of **Tonkat Ali Tonic**.

**5 How to store Tonkat Ali Tonic.**

Store at or below 25° C. Protect from light and moisture. Keep out of reach of children.

**6 Contents of the pack and other information:**

**What is in Tonkat Ali Tonic:**

The colloquial name for *Eurycoma longifolia* is Tonkat Ali. The applicable part of Tonkat Ali is the root.

The plant parts are rich in various bioactive compounds (like eurycomaoside, eurycolactone, eurycomalactone, eurycomanone, and pasakbumin-B) among which the alkaloids and quassinoids form a major portion.

A human study on senior citizens showed that Tonkat Ali has the ability to regulate sex hormones in the elderly populations of both males and females. After treatment, haemoglobin, testosterone, and dehydroepiandrosterone concentrations, and the ratio of total testosterone/cortisol and muscle force remained significantly lower in female seniors than in male seniors. Haematocrit and erythrocyte count in male seniors increased slightly but were significantly higher than in female seniors. Treatment resulted in significant increases in total and free testosterone concentrations and muscular force in men and women. The increase in free testosterone in women is thought to be due to the significant decline in sex hormone-binding globulin concentrations. Another 1-month study in 76 older men with low testosterone found that taking 200 mg of Tongkat ali extract per day significantly increased levels of this hormone to normal values in over 90% of participants. Similarly, a 12-week study in 108 men ages 30–55 observed that taking 300 mg of Tongkat Ali extract daily increased sperm volume and motility by an average of 18% and 44%, respectively.

In a rat study spanning 14 days, Tonkat Ali was shown to increase testosterone levels in rats by 30.2%. Muscle weight also increased, although not significantly. Mitochondrial Membrane Potential also increased by 25.1%. Mitochondrial membrane potential is a measure of a cell's ability to store and use energy.

Tonkat Ali is also associated with increase arousal in sexually sluggish old male rats. In another study hesitation time of middle aged rats was decreased by 2 week long exposure to *Eurycome longifolia*.

A 4-week human study showed that supplementation with Tonkat Ali improved stress hormone profile (salivary cortisol and testosterone) and certain mood parameters for tension (-11%), anger (-12%) and confusion (-15%).

The plant is also rich in quassinoids, which display a wide range of inhibitory effects, including anti-inflammatory, anti-viral, anti-malarial and anti-proliferative effects on various tumor cell types.

The other ingredients are Ethanol 62%

**What Tonkat Ali Tonic look like and contents of the pack:**

Amber glass bottle with label containing 50 ml tincture

**Holder of the certificate of registration:**

Perfectly Healthy  
4th Floor Rosebank Corner Offices  
Randburg  
2193  
063 285 9058  
[www.perfectlyhealthy.co.za](http://www.perfectlyhealthy.co.za)

**This leaflet was last revised in:**

November 2022

**Registration number:**

This medicine has not been evaluated by the South African Health Products Regulatory Authority. This medicine is not intended to diagnose, treat, cure or prevent any disease

**Access to the corresponding Professional Information**

Can be obtained on the Perfectly Healthy website

**PRODUCT INFORMATION  
COMPLEMENTARY MEDICINE**

Health Supplement

This unregistered medicine has not been evaluated by the South African Health Product Regulatory Authority for its safety, quality or intended use.

**SCHEDULING STATUS:**

S0

**1 NAME OF THE MEDICINE:**

Fibroid and Cyst Tonic (Tincture)

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION:**

Each dose (15 drops) provides: %NRV  
Eurycoma longifolia (Tonkat Ali root 10:1 extract) \*  
Ethanol 62%

Nutrient Reference Values (NRVs) for individuals 4 years and older

\*%NRV not established

Sugar free

**3 PHARMACEUTICAL FORM:**

Tincture – light brown liquid

**4 CLINICAL PARTICULARS**

**4.1 Therapeutic indications:**

Tonkat Ali Tonic is indicated as a general supplement where a deficiency of any of the ingredients exists.

**4.2 Posology and method of administration:**

Adults: 10 -15 drops, under the tongue, 3 times a day.

Children under the age of 16 years: 1 drop per age of the child, under the tongue, 2 times a day.

Keep under the tongue for 1 minute. Take with a little water if too strong to keep under the tongue

Do not exceed the recommended dose.

**4.3 Contraindications:**

If you suffer from a chronic medical condition, only use the supervision of your healthcare practitioner. If you suffer from any liver or kidney diseases or have had issues with either your liver or kidneys in the past this tonic should only be used under the supervision of a health care practitioner.

**4.4 Special warnings and precautions for use:**

Discontinue the use of this product where there is sensitivity towards any of the ingredients.

**4.5 Interaction with other medicines and other forms of interaction:**

If you are using chronic prescription medication, use it under the supervision of your healthcare practitioner. If you are taking any concomitant immunosuppressants you should only consider taking this supplement after consultation with your doctor, and do so under strict medical supervision. Discontinue use at least 2 weeks prior to undergoing planned surgical procedures.

**4.6 Fertility, pregnancy and lactation:**

Pregnant and breastfeeding women should avoid using this product.

**4.7 Effects on ability to drive and use machines:**

None or negligible

**4.8 Undesirable effects:**

Discontinue the use of this product where there is sensitivity towards any of the ingredients. The ingredients in this product may produce allergic reactions in sensitive individuals.

**4.9 Overdose:**

Symptoms of overdose include insomnia, irritability and restlessness.

**5 PHARMACOLOGICAL PROPERTIES:**

**5.1 Pharmacodynamic properties:**

Category D Complementary Medicines: Discipline Specific Traditional 33.6 – Western Herbal Medicine

Mechanism of action:

The colloquial name for Eurycoma longifolia is Tonkat Ali. The applicable part of Tonkat Ali is the root. The strength of the extract is 10:1 (extract:dried root).

The plant parts are rich in various bioactive compounds (like eurycomaoside, eurycolactone, eurycomalactone, eurycomanone, and pasakbumin-B) among which the alkaloids and quassinoids form a major portion.

A human study on senior citizens showed that Tonkat Ali has the ability to regulate sex hormones in the elderly populations of both males and females. After treatment, haemoglobin, testosterone, and dehydroepiandrosterone concentrations, and the ratio

of total testosterone/cortisol and muscle force remained significantly lower in female seniors than in male seniors. Haematocrit and erythrocyte count in male seniors increased slightly but were significantly higher than in female seniors. Treatment resulted in significant increases in total and free testosterone concentrations and muscular force in men and women. The increase in free testosterone in women is thought to be due to the significant decline in sex hormone-binding globulin concentrations. Another 1-month study in 76 older men with low testosterone found that taking 200 mg of Tongkat ali extract per day significantly increased levels of this hormone to normal values in over 90% of participants. Similarly, a 12-week study in 108 men ages 30–55 observed that taking 300 mg of Tongkat Ali extract daily increased sperm volume and motility by an average of 18% and 44%, respectively.

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A 4-week human study showed that supplementation with Tonkat Ali improved stress hormone profile (salivary cortisol and testosterone) and certain mood parameters for tension (-11%), anger (-12%) and confusion (-15%).

The plant is also rich in quassinoids, which display a wide range of inhibitory effects, including anti-inflammatory, anti-viral, anti-malarial and anti-proliferative effects on various tumour cell types.

## **5.2 Pharmacokinetic properties:**

Absorption of the ingredients is thought to be best when taken on an empty stomach.

## **5.3 Preclinical safety data:**

When taken at appropriate doses, generally considered safe. Side effects tend to be dose-related.

## **6 PHARMACEUTICAL PARTICULARS:**

### **6.1 List of excipients:**

Inactives: Ethanol 62%

### **6.2 Incompatibilities:**

Not applicable

### **6.3 Shelf life:**

24 months

### **6.4 Special precautions for storage:**

Store at or below 25° C. Protect from light and moisture. Keep out of reach of children.

### **6.5 Nature and contents of container:**

Amber glass bottle with label containing 50 ml

### **6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of such products:**

No special requirements.

## **7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Perfectly Healthy  
4th Floor Rosebank Corner Offices  
Randburg  
2193  
063 285 9058  
[www.perfectluhealty.co.za](http://www.perfectluhealty.co.za)

## **8 REGISTRATION NUMBER(S):**

This medicine has not been evaluated by the South African Health Products Regulatory Authority. This medicine is not intended to diagnose, treat, cure or prevent any disease

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:**

Not applicable

## **10 DATE OF REVISION OF TEXT:**

December 2022

## **REFERENCES**

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