

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S0

### FADOGIA AGRESTIS TESTOSTERONE 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

- **Fadogia Agrestis Testosterone Support Tonic** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **Fadogia Agrestis Testosterone Support Tonic** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **Fadogia Agrestis Testosterone Support 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 **Fadogia Agrestis Testosterone Support Tonic** is and what it is used for.
2. What you need to know before you take/ use **Fadogia Agrestis Testosterone Support Tonic**.
3. How to take /use **Fadogia Agrestis Testosterone Support Tonic**.
4. Possible side effects.
5. How to store **Fadogia Agrestis Testosterone Support Tonic**.
6. Contents of the pack and other information.

#### 1 What Female Health Support Tonic is and what it is used for:

Each dose (15 drops) provides:	%NRV
Fadogia Agrestis (Stem 10:1 extract)	*
Ethanol 62%	

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

\*%NRV not established

Sugar free

Fadogia Agrestis Testosterone Support 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 Female Health Support Tonic:

Do not take **Fadogia Agrestis Testosterone Support Tonic** if you are hypersensitive (allergic) to any of the ingredients.

#### Warnings and precautions:

Low testosterone can have negative health consequences. If you suspect that you suffer from low testosterone it is important that you seek out medical attention. Discontinue the use of this product where there is sensitivity towards any of the ingredients.

#### Other medicines and Fadogia Agrestis Testosterone Support Tonic:

If you are using chronic prescription medication, use it under the supervision of your healthcare practitioner. 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.

#### 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 **Fadogia Agrestis Testosterone Support 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 **Fadogia Agrestis Testosterone Support Tonic** affects them.

#### 3 How to take /use Fadogia Agrestis Testosterone Support Tonic.

Adults: 10 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 **Fadogia Agrestis Testosterone Support 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 **Fadogia Agrestis Testosterone Support Tonic**.

**5 How to store Fadogia Agrestis Testosterone Support 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 Fadogia Agrestis Testosterone Support Tonic:**

The applicable part of Fadogia Agrestis is the stem. The strength of the extract is 10:1 (extract:dry herb).

The aqueous extract of Fadogia agrestis stem increased the blood testosterone concentrations of rats. It is this increased testosterone levels to which its reported beneficial effects are attributed.

In an anti-inflammatory investigation it was found that Fadogia had significant dose-dependent inhibitions in the carrageenan-induced paw edema and cotton-pellet granuloma tests. The extract in the highest non-sedative dose tested (200 mg/kg) demonstrated a potency comparable with that of a reference analgesic anti-inflammatory drug, acetyl salicylate (Aspirin, 100 mg/kg). The relieving effects of Fadogia are probably mediated by the influences of active components of the extract on both central and peripheral nociceptive/antinociceptive neural mechanisms.

In addition, extracts of this plant have been shown to assist in the attenuation of biochemical, haematological and histological toxicity. Laboratory effects have also shown its anti-inflammatory and antibacterial, anti-infectant, as well as aphrodisiac properties.

The other ingredients are Ethanol 62%

**What in Fadogia Agrestis Testosterone Support 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:**

Fadogia Agrestis Testosterone Support Tonic (Tincture)

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION:**

Each dose (15 drops) provides: %NRV  
Fadogia Agrestis (Stem 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:**

Fadogia Agrestis Testosterone Support 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 drops, under the tongue, 3 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.

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

Low testosterone, especially in men, can lead to negative health affects in the long run. If you suspect that you have this condition it is important that you seek medical attention and have the condition monitored by a medical professional.

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 this tonic under the supervision of your healthcare practitioner.

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:**

Curcumin: Headaches and skin rash.

Dandelion: Diarrhoea and/or nausea, muscle aches, nausea, vaginal bleeding

**5 PHARMACOLOGICAL PROPERTIES:**

**5.1 Pharmacodynamic properties:**

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

Mechanism of action:

The applicable part of Fadogia Agrestis is the stem. The strength of the extract is 10:1 (extract:dry herb).

The aqueous extract of Fadogia agrestis stem increased the blood testosterone concentrations of rats. It is this increased testosterone levels to which its reported beneficial effects are attributed.

In an anti-inflammatory investigation it was found that Fadogia had significant dose-dependent inhibitions in the carrageenan-induced paw edema and cotton-pellet granuloma tests. The extract in the highest non-sedative dose tested (200 mg/kg) demonstrated a potency comparable with that of a reference analgesic anti-inflammatory drug, acetyl salicylate (Aspirin, 100

mg/kg). The relieving effects of Fadogia are probably mediated by the influences of active components of the extract on both central and peripheral nociceptive/antinociceptive neural mechanisms.

In addition, extracts of this plant have been shown to assist in the attenuation of biochemical, haematological and histological toxicity. Laboratory effects have also shown its anti-inflammatory and antibacterial, anti-infectant, as well as aphrodisiac properties.

The other ingredients are Ethanol 62%

## **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.perfectlyhealthy.co.za](http://www.perfectlyhealthy.co.za)

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

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

Not applicable

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

December 2022

## **REFERENCES**

- M. T. Yakubu, M. A. Akanji and A. T. Oladiji, "Aphrodisiac potentials of the aqueous extract of *Fadogia agrestis* (Schweinf. Ex Hiern) stem in male albino rats," *Complementary Medicine* ., vol. 7, no. 4, pp. 399-404, 2005.
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