

## 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

- **Female Health Support Tonic** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **Female Health Support Tonic** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **Female Health 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 **Female Health Support Tonic** is and what it is used for.
2. What you need to know before you take/ use **Female Health Support Tonic**.
3. How to take /use **Female Health Support Tonic**.
4. Possible side effects.
5. How to store **Female Health 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	
Curcuma longa (Turmeric root 10:1 extract)		*
Taraxacum officinale (Dandelion root 10:1 extract)	*	
Tribulus terrestris (Puncture vine leaf 10:1 extract)	*	
Trifolium pratense (Red clover flower 10:1 extract)	*	
Vitex agnus-castus (Chasteberry fruit 10:1 extract)	*	
Ethanol 62%		

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

\*%NRV not established

Sugar free

Female Health 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 **Female Health Support 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 Female Health Support Tonic:

If you are using chronic prescription medication, use under the supervision of your healthcare practitioner. Due to the potential hypoglycaemic effect of this product, diabetics should use this product under the supervision of their healthcare practitioner. If you are using blood thinning medication, such as warfarin, use this product 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. Diabetics should monitor blood glucose levels constantly while using this product – ingredients in this product have blood sugar lowering properties. Individuals with liver conditions should use this product under the supervision of their 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 **Female Health 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 **Female Health Support Tonic** affects them.

### **3 How to take /use Female Health Support 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **Female Health 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 **Female Health Support Tonic**.

### **5 How to store Female Health 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 Female Health Support Tonic contains:**

The applicable part of turmeric is the rhizome or roots. Turmeric's major active constituents are the curcuminoids, which include the polyphenol curcumin (diferuloylmethane), demethoxycurcumin, bisdemethoxycurcumin, calebin, and other diarylheptanoids. Some evidence suggests that curcumin has positive effects on fertility. Laboratory research suggests that curcumin protects against the death of follicular cells and improves oocyte maturation in immune ovarian failure.

The applicable parts of dandelion are the above ground parts and root. Dandelion leaves and root contain quercetin, luteolin, p-hydroxyphenylacetic acid, germacranolide acids, chlorogenic acid, chicoric acid, and monocaffeoyltartaric acid. Several laboratory studies have reported on the antioxidant properties of dandelion flower extract. The antioxidant effects of dandelion may explain some of its potential clinical effects.

The applicable parts of tribulus are the leaf, fruit, and root. Tribulus contains two major alkaloid fractions, the beta-carboline indoleamines harmine and norharmine, flavonoids, and the saponins diosgenin and protodioscin. Two steroid saponins, terrestrinins A and B, have also been isolated from tribulus. Three other steroidal saponins were isolated from tribulus in a separate study. Clinical research in premenopausal and postmenopausal adults suggests that taking tribulus daily for 90 days increases levels of free, total, and bioavailable testosterone when compared to the same dosage taken as three divided doses daily. The dosing regimen did not affect levels of prolactin, thyroid stimulating hormone, or sex hormone-binding globulin. Isoflavones found in red clover are phytoestrogens. They are structurally similar to estradiol and bind to estradiol receptors. Isoflavones have a varying affinity for estradiol receptors (estradiol-alpha and estradiol-beta) and are capable of acting as both agonists and antagonists.

The therapeutic effects of vitex agnus-castus have primarily been attributed to its indirect effects on various neurotransmitters and hormones. In females with hyperprolactinemia, vitex agnus-castus seems to suppress prolactin release. This may normalize luteal phase defects in the menstrual cycle. The linoleic acid constituent of vitex agnus-castus appears to have estrogenic effects. Vitex agnus-castus appears to be selective for beta estrogen receptors.

The other ingredients are Ethanol 62%

#### **What Female Health 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

## COMPLEMENTARY MEDICINE

### PRODUCT INFORMATION

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:

Female Health Support Tonic (Tincture)

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose (15 drops) provides:	%NRV	
Curcuma longa (Turmeric root 10:1 extract)		*
Taraxacum officinale (Dandelion root 10:1 extract)	*	
Tribulus terrestris (Puncture vine leaf 10:1 extract)	*	
Trifolium pratense (Red clover flower 10:1 extract)	*	
Vitex agnus-castus (Chasteberry fruit 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:

Female Health 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 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.

##### 4.3 Contraindications:

If you suffer from a chronic medical condition, only use the supervision of your healthcare practitioner. Diabetics should monitor blood glucose levels constantly while using this product – ingredients in this product have blood sugar lowering properties.

Individuals with liver conditions should use this product under the supervision of their healthcare 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 under the supervision of your healthcare practitioner. Due to the potential hypoglycaemic effect of this product, diabetics should use this product under the supervision of their healthcare practitioner. If you are using blood thinning medication, such as warfarin, use this product 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:

No known symptoms of overdose.

#### 5 PHARMACOLOGICAL PROPERTIES:

##### 5.1 Pharmacodynamic properties:

**Mechanism of action:**

The applicable part of turmeric is the rhizome or roots. Turmeric's major active constituents are the curcuminoids, which include the polyphenol curcumin (diferuloylmethane), demethoxycurcumin, bisdemethoxycurcumin, calebin, and other diarylheptanoids. Some evidence suggests that curcumin has positive effects on fertility. Laboratory research suggests that curcumin protects against the death of follicular cells and improves oocyte maturation in immune ovarian failure.

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The therapeutic effects of vitex agnus-castus have primarily been attributed to its indirect effects on various neurotransmitters and hormones. In females with hyperprolactinemia, vitex agnus-castus seems to suppress prolactin release. This may normalize luteal phase defects in the menstrual cycle. The linoleic acid constituent of vitex agnus-castus appears to have estrogenic effects. Vitex agnus-castus appears to be selective for beta estrogen receptors.

**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

**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:**

October 2022

**REFERENCES**

Hu C, Kitts DD. Antioxidant, prooxidant, and cytotoxic activities of solvent-fractionated dandelion (*Taraxacum officinale*) flower extracts in vitro. *J Agric Food Chem* 2003;51:301-10.  
Jarry, H., Spengler, B., Porzel, A., Schmidt, J., Wuttke, W., and Christoffel, V. Evidence for Estrogen Receptor beta-Selective Activity of Vitex agnus-castus and Isolated Flavones. *Planta Med* 2003;69(10):945-947.

Umland EM, Cauffield JS, Kirk JK, et al. Phytoestrogens as therapeutic alternatives to traditional hormone replacement in postmenopausal women. *Pharmacotherapy* 2000;20:981-90.

Vale FBC, Boroni JD, Geber G, et al. Effect of Tribulus Terrestris in the Treatment of Female Sexual Dysfunction and Clitoral Vascularization. Results of a Randomized Study Comparing Two Different Dosage Regimes. *J Sex Marital Ther* 2021;47(7):696-706

Voznesens'ka, T. I., Bryzhina, T. M., Sukhina, V. S., Makohon, N. V., and Aleksieieva, I. M. [Effect of NF-kappaB activation inhibitor curcumin on the oogenesis and follicular cell death in immune ovarian failure in mice]. *Fiziol.Zh.* 2010;56(4):96-101.