

## 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

- **Fibroid and Cyst Tonic** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use **Fibroid and Cyst Tonic** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **Fibroid and Cyst 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 **Fibroid and Cyst Tonic** is and what it is used for.
2. What you need to know before you take/ use **Fibroid and Cyst Tonic**.
3. How to take /use **Fibroid and Cyst Tonic**.
4. Possible side effects.
5. How to store **Fibroid and Cyst 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)	*	
Camellia Sinensis (Green tea 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 **Fibroid and Cyst Tonic** if you are hypersensitive (allergic) to any of the ingredients.

#### Warnings and precautions:

Both fibroids and uterine cysts can be very serious medical conditions. If you suspect that you have either of these structures it is important that you seek medical attention and have the conditions monitored by a medical professional. Discontinue the use of this product where there is sensitivity towards any of the ingredients.

#### Other medicines and Fibroid and Cyst Tonic:

If you are using chronic prescription medication, use it 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. If you are on blood pressure medications, such as beta-blockers, Digoxin, calcium channel blockers, diuretics, ACE inhibitors, and Nitrates, this product should only be used under strict supervision of a healthcare professional. 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, gallbladder problems, bleeding disorders, gastrointestinal reflux disorder, infertility, iron deficiency, heart arrhythmias, bile duct or any other intestinal obstruction, or any type of cancer 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 **Fibroid and Cyst 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 **Fibroid and Cyst Tonic** affects them.

**3 How to take /use Fibroid and Cyst 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 **Fibroid and Cyst 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 **Fibroid and Cyst Tonic**.

**5 How to store Fibroid and Cyst 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 Fibroid and Cyst Tonic:**

The colloquial name for *Curcuma longa* is turmeric. The applicable part of the *Curcuma* is the root. The strength of the extract is 10:1. Extracts of this plant have been shown to have strong anti-inflammatory and wound-healing properties. In general, *Curcuma* species produce a wide variety of volatile sesquiterpenes, monoterpenes, and other aromatic compounds. The plant is especially effective at healing diabetic wounds. Since high blood sugar levels are strongly associated with the occurrence of both fibroids and cysts in women it is believed to be the reason for its effectiveness in helping to eliminate these structures.

*Taraxacum* is colloquially known as Dandelion. The applicable part of *Taraxacum officinale* is the root. The strength of the extract is 10:1. Dandelion is known to alleviate high sugar levels. The alleviation of high sugar levels has been shown to assist with the elimination of cysts.

*Tribulus Terrestris* is colloquially known as puncture vine. The applicable part of the herb is the leaf. Its various parts contain a variety of chemical constituents which are medicinally important, such as flavonoids, flavonol glycosides, steroidal saponins, and alkaloids. The most dominant saponin in the plant is protodioscin. It has been shown to have a pro-erectile effect in the corpus cavernosum of rabbits. It has also been shown to protect the genitalia of rats by preventing pre-oxidation in this tissue. The two main components of the saponin fraction from TT, namely protodioscin and protogracillin, are responsible for the observed biological aphrodisiac activity. It is suggested that protodioscin works by increasing the conversion of testosterone into the potent dehydrotestosterone, which stimulates not only an increase in the sex drive but also the production of red cells from bone marrow along with muscular developments contributing to improvement of blood circulation and the oxygen transport systems, leading to optimal health. Saponin from TT possesses hypoglycemic properties. Balancing of glycemic levels have been proven to lower the occurrence of both fibroids and ovarian cysts.

*Trifolium pratense* is commonly known as Red clover. The applicable part of the red clover is the flower. This plant has been shown to assist in wound healing. This occurs through a combined effect of reduction in inflammation and improved blood flow, as well as the prevention of secondary infections. It has also been shown to be effective in easing physical symptoms caused by hormonal imbalances. The ability of this plant to assist in relieving symptoms of fibroids and cysts is attributed to its ability to ease the physical symptoms associated with hormonal imbalances. Red clover assists the body in healing uterine cysts by assisting wound healing.

*Vitex agnus-castes* is commonly known as Chasteberry. The applicable part of the plant is the fruit. It has been shown to regulate female reproductive hormones in numerous studies. It has also been shown to be beneficial in assisting the body to shrink irregular growths such as fibroids.

*Camellia Sinensis* is commonly known as green tea. The applicable parts are the leaves. This herb has been shown to have strong anti-cancer properties. The anti-cancer activity of the plant is attributed to surfactant and phytochemicals found in *Camellia sinensis* that enhanced the oxidation stability of healthy cell linings and enable the body to more selectively eliminate unhealthy growths.

The other ingredients are Ethanol 62%

**What Fibroid and Cyst 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	
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)	*	
Camellia Sinensis (Green tea 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:**

Fibroid and Cyst 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. Diabetics should monitor blood glucose levels constantly while using this product – ingredients in this product have blood sugar-lowering properties.

Individuals with liver conditions, gallbladder problems, bleeding disorders, gastrointestinal reflux disorder, infertility, iron deficiency, heart arrhythmias, bile duct or any other intestinal obstruction, or any type of cancer should use this product under the supervision of their healthcare practitioner.

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

Both fibroids and uterine cysts can be very serious medical conditions. If you suspect that you have either of these structures it is important that you seek medical attention and have the conditions 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 it 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. If you are on blood pressure medications, such as beta-blockers, Digoxin, calcium channel blockers, diuretics, ACE inhibitors, and Nitrates, this product should only be used under strict supervision of a healthcare professional. 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 colloquial name for *Curcuma longa* is turmeric. The applicable part of the *Curcuma* is the root. The strength of the extract is 10:1. Extracts of this plant have been shown to have strong anti-inflammatory and wound-healing properties. In general, *Curcuma* species produce a wide variety of volatile sesquiterpenes, monoterpenes, and other aromatic compounds. The plant is especially effective at healing diabetic wounds. Since high blood sugar levels are strongly associated with the occurrence of both fibroids and cysts in women it is believed to be the reason for its effectiveness in helping to eliminate these structures.

*Taraxacum* is colloquially known as Dandelion. The applicable part of *Taraxacum officinale* is the root. The strength of the extract is 10:1. Dandelion is known to alleviate high sugar levels. The alleviation of high sugar levels has been shown to assist with the elimination of cysts.

*Tribulus Terrestris* is colloquially known as puncture vine. The applicable part of the herb is the leaf. Its various parts contain a variety of chemical constituents which are medicinally important, such as flavonoids, flavonol glycosides, steroidal saponins, and alkaloids. The most dominant saponin in the plant is protodioscin. It has been shown to have a pro-erectile effect in the corpus cavernosum of rabbits. It has also been shown to protect the genitalia of rats by preventing pre-oxidation in this tissue. The two main components of the saponin fraction from TT, namely protodioscin and protogracillin, are responsible for the observed biological aphrodisiac activity. It is suggested that protodioscin works by increasing the conversion of testosterone into the potent dehydrotestosterone, which stimulates not only an increase in the sex drive but also the production of red cells from bone marrow along with muscular developments contributing to improvement of blood circulation and the oxygen transport systems, leading to optimal health. Saponin from TT possesses hypoglycemic properties. Balancing of glycemic levels have been proven to lower the occurrence of both fibroids and ovarian cysts.

*Trifolium pratense* is commonly known as Red clover. The applicable part of the red clover is the flower. This plant has been shown to assist in wound healing. This occurs through a combined effect of reduction in inflammation and improved blood flow, as well as the prevention of secondary infections. It has also been shown to be effective in easing physical symptoms caused by hormonal imbalances. The ability of this plant to assist in relieving symptoms of fibroids and cysts is attributed to its ability to ease the physical symptoms associated with hormonal imbalances. Red clover assists the body in healing uterine cysts by assisting wound healing.

*Vitex agnus-castes* is commonly known as Chasteberry. The applicable part of the plant is the fruit. It has been shown to regulate female reproductive hormones in numerous studies. It has also been shown to be beneficial in assisting the body to shrink irregular growths such as fibroids.

*Camellia Sinensis* is commonly known as green tea. The applicable parts are the leaves. This herb has been shown to have strong anti-cancer properties. The anti-cancer activity of the plant is attributed to surfactant and phytochemicals found in *Camellia sinensis* that enhanced the oxidation stability of healthy cell linings and enable the body to more selectively eliminate unhealthy growths.

### **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**

Bibliography

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