

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

ULCER CARE 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

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

1 What Ulcer Care Tonic is and what it is used for:

Each dose (15 drops) provides:	%NRV
Althaea officinalis (Marshmallow root 10:1 extract)	*
Ulmus rubra (Slippery elm inner root 10:1 extract)	*
Glycyrrhiza glabra (Liquorice root 10:1 extract)	*
Curcuma longa (Turmeric root 10:1 extract)	*
Chamaemelum nobile (Chamomile flower 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 Ulcer Care Tonic:

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

Warnings and precautions:

Stomach ulcers can be very serious medical conditions. If you suspect that you have a stomach ulcer 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.

Other medicines and Ulcer Care Tonic:

If you are using chronic prescription medication, use it under the supervision of your healthcare practitioner. This product may interfere with the absorption of other medications and should be taken several hours before any other medication is taken. 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 who have liver problems should take this medication under the strict supervision of a healthcare practitioner. Individuals with low or high blood pressure should or low blood potassium levels should use this medication under the supervision of a medical professional. Individuals with coronary artery disease, abnormal heart rhythms, or chronic heart failure should take this medication under the supervision of a medical professional. Individuals with bile duct blockages should take this medication under the supervision of a 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 **Ulcer Care 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 **Ulcer Care Tonic** affects them.

3 How to take /use Ulcer Care 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 **Ulcer Care Tonic**.

5 How to store Ulcer Care 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 Ulcer Care Tonic:**

Althaea Officinalis is commonly known as Marshmallow. The applicable part of the plant is the root. The Marshmallow plant has an ability to coat the stomach. In a laboratory study *Althaea officinalis* pretreatments fixed blood and tissue biomarkers, thereby protecting them from pyloric-ligation/indomethacin-induced gastric-ulceration in rats.

Ulmus Rubra is commonly known as slippery elm. The applicable part of the plant is the inner bark. The inner part of the bark causes a protective lining to form on mucus with which it comes into contact.

The common name for *Glycyrrhiza glabra* L. is liquorice root. The applicable part of this plant is the root. Glycyrrhizin is generally regarded as the major biologically-active principle. This active ingredient has been shown in laboratory studies to assist in wound healing and to reduce inflammation related pain in mucosal tissue.

Matricaria chamomilla L. is more commonly known as chamomile. The applicable part of the plant is the flower. The flowers of this plant contain bisabolol. Bisabolol has been found to reduce the amount of proteolytic enzyme pepsin secreted by the stomach without any change occurring in the amount of stomach acid, due to which it has been recommended for the treatment of gastric and upper intestinal diseases.

Curcuma Longa is more commonly known as Tumeric. The applicable part of the plant is its root. Extracts of this plant have strong anti-bacterial properties and has been shown to be effective in killing *Helicobacter Pylori* (H. Pylori), which is the bacteria thought to be responsible for the occurrence of stomach ulcers.

The other ingredients are Ethanol 62%

What Ulcer Care 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

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:

Ulcer Care Tonic (Tincture)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each dose (15 drops) provides:	%NRV
Althaea officinalis (Marshmallow root 10:1 extract)	*
Ulmus rubra (Slippery elm inner root 10:1 extract)	*
Glycyrrhiza glabra (Licorice root 10:1 extract)	*
Curcuma longa (Turmeric root 10:1 extract)	*
Chamaemelum nobile (Chamomile flower 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:

Ulcer Care 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. This product may interfere with the absorption of other medications and should be taken several hours before any other medication is taken. 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:

Possible symptoms of overdose include:

- Headaches
- Skin rash

- 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:

Althaea Officinalis is commonly known as Marshmallow. The applicable part of the plant is the root. The Marshmallow plant has an ability to coat the stomach. In a laboratory study *Althaea officinalis* pretreatments fixed blood and tissue biomarkers, thereby protecting them from pyloric-ligation/indomethacin-induced gastric-ulceration in rats.

Ulmus Rubra is commonly known as slippery elm. The applicable part of the plant is the inner bark. The inner part of the bark causes a protective lining to form on mucus with which it comes into contact.

The common name for *Glycyrrhiza glabra* L. is liquorice root. The applicable part of this plant is the root. Glycyrrhizin is generally regarded as the major biologically-active principle. This active ingredient has been shown in laboratory studies to assist in wound healing and to reduce inflammation related pain in mucosal tissue.

Matricaria chamomilla L. is more commonly known as chamomile. The applicable part of the plant is the flower. The flowers of this plant contain bisabolol. Bisabolol has been found to reduce the amount of proteolytic enzyme pepsin secreted by the stomach without any change occurring in the amount of stomach acid, due to which it has been recommended for the treatment of gastric and upper intestinal diseases.

Curcuma Longa is more commonly known as Tumeric. The applicable part of the plant is its root. Extracts of this plant have strong anti-bacterial properties and has been shown to be effective in killing *Helicobacter Pylori* (*H. Pylori*), which is the bacteria thought to be responsible for the occurrence of stomach ulcers.

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:

December 2022

REFERENCES

- S. S. Zaghlool, A. A. Abo-Seif, M. A. Rabeh, U. R. Abdelmohsen and B. A. S. Messiha, "Gastro-Protective and Anti-Oxidant Potential of *Althaea officinalis* and *Solanum nigrum* on Pyloric Ligation/Indomethacin-Induced Ulceration in Rats," *Antioxidants Base*, vol. 8, no. 11, p. 512, 2019.
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- G. R. Fenwick, J. Lutomski and C. ieman, "Liquorice, *Glycyrrhiza glabra* L.—Composition, uses and analysis," *Food Chemistry*, vol. 38, no. 2, pp. 119-143, 1990.
- O. Singh, Z. Khanam, N. Misra and M. K. Srivastava, "Chamomile (*Matricaria chamomilla* L.): An overview," *Pharmacognosy review*, vol. 5, no. 9, pp. 82-95, 2011.
- N. M. Khanna, "Turmeric - Nature's precious gift," *Current Science*, vol. 76, no. 10, pp. 1351-1356, 1999.