

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

APPETITE AND WEIGHT GAIN 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

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

1 What Appetite and Weight Gain Tonic is and what it is used for:

Each dose (15 drops) provides:	%NRV
Gentia Lucea (Yellow Gentia root 10:1 extract)	*
Matricaria Chamomilla (German Chamomile flower 10:1 extract)	*
Taraxacum Officinale (Dandelion root 10:1 extract)	*
Withania somnifera (Ashwaganda root 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 Appetite and Weight Gain Tonic:

Do not take **Appetite and Weight Gain Tonic** if you are hypersensitive (allergic) to any of the ingredients.

Warnings and precautions:

This product contains liquorice root. In rare cases, liquorice root can cause mineralocorticoid excess (AME) syndrome. AME is expressed as sodium retention, potassium loss and suppression of the renin-angiotensin-aldosterone system. It results in raised blood pressure and oedema. Please contact your doctor if you exhibit any of these symptoms.

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

Other medicines and Appetite and Weight Gain 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. Discontinue use at least 2 weeks prior to undergoing planned surgical procedures.

Do not use this product if you are on anti-biotics. People who are on blood thinners need to use this medication under the supervision of their doctor.

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. If you suffer from heart disease or high blood pressure, or kidney disease this product should be used under the supervision of your doctor. If you suffer from low blood pressure please speak to your doctor before taking this medication.

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 **What Appetite and Weight Gain 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 **What Appetite and Weight Gain Tonic** affects them.

3 How to take /use What Appetite and Weight Gain 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 **What Appetite and Weight Gain 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 **What Appetite and Weight Gain Tonic**.

5 How to store What Appetite and Weight Gain 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 What Appetite and Weight Gain Tonic:**

The common name of Gentia Lutea is Yellow gentia. The applicable part of the plant is the root. [1]The dried gentian root contains gentiasein, gentisin, iso-gentisin, gentinin and gentiamarin, bitter glycosides, together with gentianic acid (gentisin), the later being physiologically inactive. Yellow Gentia has been shown to increase bile flow of rats in which bile flow was impaired. Gentia Lutea L is used in this tonic for its ability to improve bile flow.

The common name of Glycyrrhiza glabra is liquorice. The applicable part of this plant is the root. The plant is understood to assist in reducing gastrointestinal discomfort associated with improper digestion of food due to the presence of glycyrrhizin. Glycyrrhin can raise the concentration of prostaglandins in the digestive tract, which has been shown to promote stomach mucus secretion.

The common name for Matricaria Chamomilla is German Chamomile. Active principles of German chamomile are terpenoids: α -bisabolol, α -bisabolol oxide A and B, chamazulene, sesquiterpenes; coumarins: umbelliferone; flavonoids: luteolin, apigenin, quercetin; spiroethers: en-yn dicycloether and other components such as tannins, anthemic acid, choline, polysaccharides and phytoestrogens. The flowers of this plant have a spasmolytic effect. This means that they reduce spasms of the gastrointestinal tracts that leads to digestion related pain and suppressed appetite.

Taraxacum officinale is commonly known as dandelion. The applicable part of this plant is the roots and leaves. contains anti-angiogenic, anti-inflammatory and anti-nociceptive activities through its inhibition of NO production and COX-2 expression and/or its antioxidative activity.

The common name of Withania somnifera is ashwagandha. The applicable part of the plant is the root. This plant is known to have positive effects on the mood of patient who take them and was added to assist in mood-related suppression of appetite. The other ingredients are Ethanol 62%

What What Appetite and Weight Gain 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 (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

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 who have liver problems should take this medication under the strict supervision of a healthcare practitioner. If you suffer from heart disease or high blood pressure, or kidney disease this product should be used under the supervision of your doctor. If you suffer from low blood pressure please speak to your doctor before taking this medication.

4.4 Special warnings and precautions for use:

This product contains liquorice root. In rare cases, liquorice root can cause mineralocorticoid excess (AME) syndrome. AME is expressed as sodium retention, potassium loss and suppression of the renin-angiotensin-aldosterone system. It results in raised blood pressure and oedema. Please contact your doctor if you exhibit any of these symptoms.

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. Discontinue use at least 2 weeks prior to undergoing planned surgical procedures.

Do not use this product if you are on anti-biotics. People who are on blood thinners need to use this medication under the supervision of their doctor.

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:

The common name of Gentia Lutea L is Yellow gentia. The applicable part of the plant is the root. [1]The dried gentian root contains gentisein, gentisin, iso-gentisin, gentinin and gentiamarin, bitter glycosides, together with gentianic acid (gentisin), the later being physiologically inactive. Yellow Gentia has been shown to increase bile flow of rats in which bile flow was impaired. Gentia Lutea L is used in this tonic for its ability to improve bile flow.

The common name of Glycyrrhiza glabra is liquorice. The applicable part of this plant is the root. The plant is understood to assist in reducing gastrointestinal discomfort associated with improper digestion of food due to the presence of glycyrrhizin. Glycyrrhin can raise the concentration of prostaglandins in the digestive tract, which has been shown to promote stomach mucus secretion.

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Taraxacum officinale is commonly known as dandelion. The applicable part of this plant is the roots and leaves. contains anti-angiogenic, anti-inflammatory and anti-nociceptive activities through its inhibition of NO production and COX-2 expression and/or its antioxidative activity.

The common name of Withania somnifera is ashwagandha. The applicable part of the plant is the root. This plant is known to have positive effects on the mood of patients who take them and was added to assist in mood-related suppression of appetite.

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):

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

Not applicable

10 DATE OF REVISION OF TEXT:

December 2022

REFERENCES

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- S. Sharafzadeh and O. Alizadeh, "German and Roman Chamomile," *Journal of applied pharmaceutical science*, vol. 10, pp. 01-05, 2011.
- H. J. Jeon, H. J. Kang, Y. S. Kang, K. C. J. Lim, Y. M. Kim and E. H. Park, "Anti-inflammatory activity of *Taraxacum officinale*," *Journal of Ethnopharmacology*, vol. 115, no. 1, pp. 82-88, 2008.
- D. Donaldson and A. Olukogwa, "Liquorice and its health implications," *Royal society for public health*, vol. 120, no. 2, 2000.
- G. Pastorino, L. Cornara, S. Soares, F. Rodrigues and B. P. P. Oliveira, "Liquorice (*Glycyrrhiza glabra*): A phytochemical and pharmacological review," *Wiley Public Health Emergency Collection*, vol. 32, no. 12, p. 2323–2339, 2018.