PROFESSIONAL INFORMATION

33.6 WESTERN HERBAL MEDICINE. Complementary Medicine

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

TONY FERGUSON CRANBERRY CONCENTRATE (liquid)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml serving contains:	
Vaccinium macrocarpon (Cranberry)	600,00 mg
[fruit, as 150,00 mg of a 4:1 extract]	

Contains sweetener: 10 mg sucralose per 10 ml serving.

Contains sugar alcohol: 2 g sorbitol and 1 g glycerol per 10 ml serving.

Contains preservatives: sodium benzoate (0,05%), sodium metabisulphate (0,05%), potassium sorbate (0,04%).

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid.

Reddish-brown liquid with a cranberry-berry flavour.

This product contains herbal extracts which may differ in colour and taste from batch to batch.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TONY FERGUSON CRANBERRY CONCENTRATE SYRUP is a complementary medicine that:

- Provides a source of antioxidants.
- Supports urinary tract health.
- Helps to prevent recurrent urinary tract infections.

4.2 Posology and method of administration

Posology

Adults 18 years and older: Take 10 ml per day, or as directed by a healthcare provider.

Can be taken directly as is or diluted in water to taste.

Use for at least 4 weeks to see beneficial effects.

SHAKE THE BOTTLE WELL BEFORE USE.

Do not exceed the recommended dose.

Method of administration

For oral use.

4.3 Contraindications

• Hypersensitivity to any of the active ingredients listed in section 2 or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Patients with a history of kidney stones, as cranberry contains oxalate which could increase the risk of developing kidney stones.
- Patients with aspiring allergy or asthma.

4.5 Interaction with other medicines and other forms of interaction

- Atorvastatin: cranberry may increase the levels and adverse effects of atorvastatin.
- Nifedipine: cranberry may increase the levels and adverse effects of nifedipine.
- Warfarin: cranberry may increase the levels and adverse effects of warfarin.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Patients should exercise caution before driving or operating machinery until they are reasonably certain TONY FERGUSON CRANBERRY CONCENTRATE SYRUP does not adversely affect their performance.

4.8 Undesirable effects

TONY FERGUSON CRANBERRY CONCENTRATE SYRUP is generally well tolerated when taken at the recommended dose.

Gastrointestinal disorders

Frequency unknown: gastrointestinal upset, diarrhoea, nausea, vomiting.

Genitourinary disorders

Frequency unknown: vulvovaginal candidiasis, vaginal itching, vaginal dryness, excessive urination, nocturia.

Skin and subcutaneous tissue disorders

Frequency unknown: skin redness and itching.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: Category D 33.6 Western Herbal Medicine. Complementary Medicine.

TONY FERGUSON CRANBERRY CONCENTRATE SYRUP is a complementary medicine that:

- Provides a source of antioxidants.
- Supports urinary tract health.
- Helps to prevent recurrent urinary tract infections.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on TONY FERGUSON CRANBERRY CONCENTRATE SYRUP.

Absorption: After intake of cranberry juice, plasma phenol levels peaked at 1 hour, and vitamin C concentrations reached a plateau at 2 hours. Maximum levels of anthocyanins in plasma occurred between one to three hours after cranberry juice ingestion. In the plasma, concentrations of anthocyanins were between 0.56 and 4.64 nmol/L.

Elimination: Healthy volunteers who ingested 200 mL of cranberry juice excreted 6 of 12 anthocyanins identified in cranberry in their urine at 24 hours, although the maximum anthocyanin excretion occurred between 3 and 6 hours after ingestion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water

Citric Acid

Xanthan Gum

Flavouring

Calcium EDTA (E385)

Colourant (E122)

Sucralose

Sorbitol

Glycerine

Sodium Benzoate

Sodium Metabisulphate

Potassium Sorbate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months from date of manufacturing.

6.4 Special precautions for storage

Store at or below 25 °C.

Store in a dry place away from direct sunlight and moisture.

Store in the original package until required for use.

Do not use after the expiry date stated on the label.

Return all unused TONY FERGUSON CRANBERRY CONCENTRATE SYRUP to your pharmacist.

Do not dispose of unused TONY FERGUSON CRANBERRY CONCENTRATE SYRUP in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents of container

Amber glass container with a white, ribbed screw-on cap.

Pack sizes: 500 ml.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for Tony Ferguson Weightloss SA (Pty) Ltd. 686 Carradale
Crescent, Cedar Creek Estate
Needwood Ext. 8
Broadacres, Johannesburg
South Africa
2191
info@tonyferguson.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.