

**PROFESSIONAL INFORMATION**

**COMPLEMENTARY MEDICINE: COMBINATION PRODUCT**

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

**SCHEDULING STATUS**

**S0**

**1. NAME OF THE MEDICINE**

**TONY FERGUSON CHROMIUM PLUS (tablets)**

**1. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains:

<i>Cinnamomum cassia</i> (L.) J. Presl (Cinnamon) [bark, 4:1 extract providing 500 mg dried herb equivalent]	125 mg
Ascorbic Acid (Vitamin C)	50 mg
Chromium Picolinate	1207 µg
Providing Chromium (elemental)	150 µg

Sugar free.

For full list of excipients, see section 5.1.

**2. PHARMACEUTICAL FORM**

Tablets.

Pink, round, concave film-coated tablets.

**3. CLINICAL PARTICULARS**

**3.1 Therapeutic indications**

TONY FERGUSON CHROMIUM PLUS provides chromium, a mineral which supports healthy glucose metabolism for the maintenance of normal blood sugar levels. Cinnamon and vitamin C are supportive antioxidants.

### 3.2 Posology and method of administration

#### Posology

**Adults 18 years and older:** Take 1 tablet daily in the morning with food, or as recommended by a healthcare provider.

Not suitable for children.

Swallow the tablet whole and do not chew or crush.

Do not exceed the recommended dose.

#### Method of administration

For oral use. To be taken with food.

### 3.3 Contraindications

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

### 3.4 Special warnings and precautions for use

- Use with caution in patients with any medical conditions or who are taking any other medications.
- Use with caution in patients who have a liver or kidney disease.
- Use with caution in patients who have diabetes.
- Use with caution in patients who have a psychiatric disorder.
- Tell patients to discontinue using TONY FERGUSON CHROMIUM PLUS at least two weeks prior to elective surgical procedures.

### 3.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on TONY FERGUSON CHROMIUM PLUS. Not all possible interactions are indicated in this leaflet.

#### Cassia cinnamon:

- **Antidiabetes medication:** cassia cinnamon may have additive effects when used with antidiabetes medication.
- **Hepatotoxic medication:** large doses of cassia cinnamon might cause additive effects when used with hepatotoxic medications. Caution is advised for those with liver disease or those currently taking potentially hepatotoxic agents.

#### Ascorbic acid:

- **Alkylating agents:** the antioxidant effects of vitamin C may reduce the effectiveness of alkylating agents.
- **Aluminium:** vitamin C can increase the amount of aluminium absorbed from aluminium compounds.
- **Antitumour antibiotics:** the antioxidant effects of vitamin C may reduce the effectiveness of antitumour antibiotics.

- **Estrogens:** vitamin C might increase blood levels of estrogens.
- **Fluphenazine:** vitamin C might decrease levels of fluphenazine.
- **Indinavir:** vitamin C can modestly reduce indinavir levels.
- **Levothyroxine:** vitamin C can increase levothyroxine absorption.
- **Warfarin:** high doses of vitamin C may reduce the levels and effectiveness of warfarin.

**Chromium:**

- **Antidiabetes medication:** chromium may have additive effects with antidiabetic agents and can thereby increase the risk of hypoglycaemia.
- **Insulin:** concomitant use of chromium and insulin might increase the risk of hypoglycaemia.
- **Levothyroxine:** chromium might bind levothyroxine in the intestinal tract and decrease levothyroxine absorption.

**3.6 Fertility, pregnancy and lactation**

Patients who are pregnant or think they may be pregnant should not use TONY FERGUSON CHROMIUM PLUS.

Patients who are breastfeeding should consult a healthcare practitioner prior to using TONY FERGUSON CHROMIUM PLUS.

**3.7 Effects on ability to drive and use machines**

Patients should take caution before performing activities requiring their attention, until they are reasonably certain that TONY FERGUSON CHROMIUM PLUS does not adversely affect their performance.

**3.8 Undesirable effects**

TONY FERGUSON CHROMIUM PLUS is generally well tolerated.

**Gastrointestinal disorders**

*Frequency unknown:* nausea, vomiting, diarrhoea, changes in appetite, constipation, flatulence, stomach upset, stomach cramps, heartburn.

**Endocrine disorders**

*Frequency unknown:* hypoglycaemia.

**Nervous system disorders**

*Frequency unknown:* headache, paresthesia, insomnia, dizziness, vertigo.

**Psychiatric disorders**

*Frequency unknown:* irritability, mood changes.

**Skin and subcutaneous tissue disorders**

*Frequency unknown:* skin rash, hives.

### **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 asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

### **3.9 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.

## **4. PHARMACOLOGICAL PROPERTIES**

### **4.1 Pharmacodynamic properties**

**Class and category:** Category D 33.7 Combination Product.

#### **Cassia cinnamon**

Cassia cinnamon provides antioxidants which can help protect cells from oxidation through its free radical scavenging effects.

#### **Ascorbic acid**

Ascorbic acid is an antioxidant that helps to protect cells from oxidation.

#### **Chromium**

Chromium contributes to the maintenance of normal blood glucose levels and towards the metabolism of macronutrients.

### **4.2 Pharmacokinetic properties**

Pharmacokinetic studies have not been conducted on TONY FERGUSON CHROMIUM PLUS.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 List of excipients**

*Core:*

Di-Calcium Phosphate

Povidone

Magnesium Stearate

*Film-Coating:*

Polyvinyl alcohol polyethylene  
Talc  
Titanium dioxide  
Erythrosine

## **5.2 Incompatibilities**

Not applicable.

## **5.3 Shelf Life**

24 months.

## **5.4 Special precautions for storage**

Store at or below 25 °C.  
Store in a dry place away from direct sunlight and moisture.  
Keep tablets in the container until required for use.

## **5.5 Nature and contents of container**

White PET container with a white screw cap lid.  
Pack size: 60 tablets.

## **5.6 Special precautions for disposal**

No special requirements.

## **6. HOLDER OF CERTIFICATE OF REGISTRATION**

Tony Ferguson Weightloss SA (Pty) Ltd.  
686 Carradale Crescent  
Cedar Creek Estate  
Needwood Ext. 8  
Broadacres, Johannesburg  
South Africa  
2191

## **7. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

## **8. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.