

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL

FORM - TESTRALIN®, 60 Tablets

COMPOSITION

Each one (1) tablet of TESTRALIN® contains the following actives:

Decaffeinated Green Tea (Camellia sinensis) [Leaf Extract standardized to 60 % (100 mg) catechins and 40 % (67 mg) epigallocatechin gallate (EGCG)]	167 mg
Turmeric (Curcuma longa) [Rhizome 25:1 Extract standardized to 95 % (75 mg) curcuminoids]	79 mg
Soybean (Glycine max) Concentrate Phytosterols (providing beta-sitosterol 24.5 mg, 50 mg campesterol 12 mg, stigmasterol 9.3 mg and other plant sterols 4,2 mg)	62.5 mg
Betaine (as betaine HCl) Lignans [as secoisolariciresinol diglucosides; (SDG)] 25 mg [from 125 mg flaxseed extract (Linum usitatissimum)] Total Isoflavones (containing all forms of genistin, 25 mg daidzin and glycitin)	37.5 mg
Vitamin B6 (as pyridoxine HCl)	25 mg
Oleonic Acid [from olive (Olea europaea) leaf extract]	5 mg
Lycopene 5 mg Zinc (as zinc citrate)	2.5 mg
Folate (as calcium L-5-methyltetrahydrofolate)	200 µg
Selenium (as selenomethionine)	100 µg
Vitamin B12 (as methylcobalamin)	15 µg
Vitamin D (as cholecalciferol)	9.4 µg (375 I.U.)

Inactive Ingredients: Calcium silicate, coating [hypromellose, hydroxypropylcellulose, medium-chain triglycerides, and sodium copper chlorophyllin (colour)], croscarmellose sodium, microcrystalline cellulose, silica, stearic acid (vegetable).

This product is dairy and gluten free and non-GMO (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

TESTRALIN® supports overall health with a blend of antioxidants, vitamins, and plant extracts. Formulated with ingredients such as green tea extract, turmeric, and phytonutrients like phytosterols, lignans, and lycopene to assist the body's natural antioxidant defences and support general well-being.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take TESTRALIN® if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement. **Surgery:** TESTRALIN® might increase the risk of bleeding during and after surgery. Stop using TESTRALIN® at least 2 weeks before a scheduled surgery. **Laboratory tests:** May interfere with the results of many different blood lab tests. TESTRALIN® can cause falsely high or falsely low test results. This might lead to missed or incorrect diagnoses. Tell your doctor if you are taking this supplements, especially if you are having lab tests done. **Antibiotics:** Take your antibiotics 2 hours before or 4 hours after taking TESTRALIN®.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See Warnings & Special precautions)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take one (1) tablet daily with food or as directed by your healthcare practitioner. Do not take more than the recommended dose.

Ingredient	Use for Ingredient
Decaffeinated Green Tea (Camellia sinensis)	Supports metabolism, weight loss, and heart health.
Turmeric (Curcuma longa)	Reduces inflammation, supports digestion, and liver health.
Soybean (Glycine max) Concentrate Phytosterols	Lowers cholesterol and supports heart health.
Betaine (as betaine HCl) Lignans	Aids digestion and supports liver function.
Vitamin B6 (as pyridoxine HCl)	Supports brain function, mood, and red blood cell production.
Oleonic Acid (Olea europaea)	Supports immune health, liver detox, and has anti-inflammatory properties.
Lycopene	Protects prostate health and provides antioxidant benefits.
Zinc (as zinc citrate)	Supports immune function, skin health, and metabolism.
Folate (as calcium L-5-methyltetrahydrofolate)	Essential for DNA synthesis, red blood cells.
Selenium (as selenomethionine)	Supports immune health, thyroid function, and reduces oxidative stress.
Vitamin B12 (as methylcobalamin)	Supports nerve function, red blood cells, and energy metabolism.
Vitamin D (as cholecalciferol)	Supports bone health, immune function, and calcium absorption.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects. **Treatment:** Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Liver disease (due to EGCG's potential hepatotoxicity), Gallbladder disease (due to choleretic effect), Hormone-sensitive conditions (e.g., breast, ovarian cancer) due to phytoestrogenic activity, Gastric ulcers or peptic ulcers, Severe liver or kidney disorders, Hypercalcemia, kidney stones, Hyperparathyroidism. If you are taking the following medication, please consult with your healthcare professional before taking: May interact with anticoagulants (e.g., warfarin), Potential interaction with diabetes medications (may lower blood sugar), May interact with thyroid hormone medications (levothyroxine). Can affect absorption of fat-soluble drugs, May interact with drugs that affect liver or kidney function (e.g., ACE inhibitors), May interact with oestrogen-sensitive medications (e.g., tamoxifen), May interfere with thyroid function, May interact with levodopa (Parkinson's medication), Can reduce the effectiveness of certain anti-TB drugs, May interact with antihypertensive medications, May interact with chemotherapy agents, May interact with certain medications (e.g., metformin), May interact with certain medications (e.g., corticosteroids, anticonvulsants). If any of the following happens, stop using TESTRALIN® and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions – rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;

These are all very serious effects. If you have them, you may have had a serious reaction to TESTRALIN®. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, flatulence, fatigue.
- These are all very serious effects. If you have them, you may have had a serious reaction to TESTRALIN®. You may need urgent medical attention or hospitalisation. Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur. Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.
- Keep this leaflet. You may need to read it again.
 - Do not share medication with any other person.
 - Ask your pharmacist if you need more information or advice.
 - You must consult a doctor should your condition worsen or does not improve. DO NOT USE THIS PRODUCT:
 - If you are hypersensitive (allergic) to any of the ingredients listed.
 - Do not accept this package if seals are broken.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C. Protect from direct sunlight and heat. Store in the original bottle. Keep the bottle tightly closed.

Replace the protective cap after each use. Do not use after the expiry date stated on the bottle. Do not use TESTRALIN® if you notice visible signs of deterioration.

IDENTIFICATION

Green coated tablet.

PRESENTATION

A white 250 mL HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Ampro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

TESTRALIN[®], 60 Tablette

SAMESTELING

Elke een (1) tablet van TESTRALIN[®] bevat die volgende aktiewe stowwe:

Kafeienvrye groen tee (Camellia sinensis)	167 mg
[Blaarekstrak gestandaardiseer tot 60% (100 mg) kateiene en 40% (67 mg) epigallocatechin gallate (EGCG)]	
Borrie (Curcuma longa) [Risoem 25: 1 Uittreksel gestandaardiseer tot 95% (75 mg) curcuminoïede]	79 mg
Sojabone (Glycine max) Konsentraat Fitosterole (verskaf beta-sitosterol 24,5 mg, 50 mg campesterol 12 mg, stigmasterol 9,3 mg en ander plantsterole 4,2 mg)	62,5 mg
Betaine (as betaine HCl) Lignane [as secosilicicresinol diglukosiede; (SDG)] 25 mg [van 125 mg vlasaad uittreksel (Linum usitatissimum)]	37,5 mg
Totale Isoflavone (wat alle vorme van genistien, 25 mg daidzin en glisitin bevat)	
Vitamien B6 (as piridoksien HCl)	25 mg
Oleanoosuur [van olywe (Olea europaea) blaarekstrak]	5 mg
Likopeen 5 mg sink (as sinkitraat)	2,5 mg
Folaat (as kalsium L-5-metiltetrahidrofolaat)	200 µg
Selenium (as selenometionien)	100 µg
Vitamien B12 (as metielkobalamien)	15 µg
Vitamien D (as cholecalciferol)	9,4 µg (375 IE)

Onktiewe bestanddele: Kalsiumsilikaat, bedekking [hipromellose, hidroksipropylselulose, mediumketting trigliseriede en natrium koperchlorofillien (kleur)], crosarmellose-natrium, mikrokristallyn selulose, silika, steariensuur (groente).

Hierdie produk is suiwel- en glutenvry en nie-GGO (suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

TESTRALIN[®] ondersteun algemene gesondheid met 'n mengsel van antioksidante, vitamien en plantektrakte. Geformuleer met bestanddele soos groen tee-ekstrak, borrie en fitonutriënte soos fitosterole, lignane en likopeen om die liggaam se natuurlike antioksidantverdediging te help en algemene welstand te ondersteun.

Bestanddeel	Gebruik vir bestanddeel
Kafeienvrye groen tee (Camellia sinensis)	Ondersteun metabolisme, gewigsverlies en hartgesondheid.
Borrie (Curcuma longa)	Verminder inflammasie, ondersteun spysvertering en lewergesondheid.
Sojabone (Glycine max) Konsentraat Fitosterole	Verslaag cholesterol en ondersteun hartgesondheid.
Betaine (as betaine HCl) Lignane	Help vertering en ondersteun lewerfunksie.
Vitamien B6 (as piridoksien HCl)	Ondersteun breinfunksie, bui en rooibloedselproduksie.
Oleanoosuur (Olea europaea)	Ondersteun immuungesondheid, lewerdetoks, en het anti-inflammatoriese eienskappe.
Likopeen	Beskerm prostaatgesondheid en bied antioksidante voordele.
Sink (as sinkitraat)	Ondersteun immuunfunksie, velgesondheid en metabolisme.
Folaat (as kalsium L-5-metiltetrahidrofolaat)	Noodsaaklik vir DNA-sintese, rooibloedselle.
Selenium (as selenometionien)	Ondersteun immuungesondheid, skildklierfunksie en verminder oksidatiewe stres.
Vitamien B12 (as metielkobalamien)	Ondersteun senuweefunksie, rooibloedselle en energiemetabolisme.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **TESTRALIN[®]** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

Chirurgie: **TESTRALIN[®]** kan die risiko van bloeding tydens en na die operasie verhoog. Hou op om **TESTRALIN[®]** ten minste 2 weke voor 'n geskeduleerde operasie te gebruik. **Laboratoriumtoets:** Kan innemig met die resultate van baie verskillende bloedlaboratoriumtoets. **TESTRALIN[®]** kan vals hoë of vals lae toetsresultate veroorsaak. Dit kan lei tot gemiste of verkeerde diagnoses. Vertel jou dokter as jy hierdie aanvullings neem, veral as jy laboratoriumtoets laat doen. **Antibiotika:** Neem jou antibiotika 2 ure voor of 4 ure na die neem van **TESTRALIN[®]**.

INTERAKSIE

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem een (1) tablet daaglik saam met kos of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gedignoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Lewersiekte (as gevolg van EGCG se potensieel hepatotoksiesiteit), Galblaasiekte (as gevolg van choleretiese effek), Hormoonseiwetige toestande (bv. borskanker, eierstokkanker) as gevolg van fitoestrogeniese aktiwiteit, maagere of maagere, Ernstige lewer- of nierafwykings, Hiperkalsemie, idney stene, Hiperparatiroidisme. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Kan interaksie hê met antihipertensiewe medikasie, Kan interaksie hê met diabetesmedikasie (kan bloedsuiker verlaag), Kan interaksie hê met skildklierhormoonmedikasie (levotiroksien), Kan absorpsie van vetoplosbare middels beïnvloed, Kan interaksie hê met middels wat lewer- of nierfunksie beïnvloed (bv. Kan interaksie hê met estrogen-sensitiewe medikasie (bv. tamoxifen), Kan innemig met skildklierfunksie, Kan interaksie hê met levodopa (Parkinson se medikasie), Kan die doeltreffendheid van sekere anti-TB-middels verminder, Kan interaksie hê met anti-hiptensiewe medikasie, Kan interaksie hê met chemoterapiemiddels, Kan interaksie hê met sekere medisyne. As enige van die volgende gebruik, hou op om **TESTRALIN[®]** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies-uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **TESTRALIN[®]** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Niewe-efekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid/braking, windrigheid, moegheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **TESTRALIN[®]** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.

- Moenie medisyne met enige ander persoon deel nie.

- Vra jou apteker of jy meer inligting of advies benodig.

- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.

- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige newe-efekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN

Sien newe-efekte.

Behandeling: Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **TESTRALIN[®]** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Groen bedekte tablet.

AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSDRANS VAN APPLIKANT

Versprei deur: Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension, Sandton, 2146

Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.