

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

### THYROSOL, 90 Capsules

#### COMPOSITION

Each one (1) capsule of THYROSOL contains the following actives:

Inositol (as myo-inositol)	200 mg
Rhodiola (Rhodiola rosea L.) [Rhizome Extract standardized to 1% (1,33 mg) salidroside and 3% (4,0 mg) rosavin's]	133 mg
Vitamin E (as d-alpha-tocopheryl succinate)	44,7 mg
Magnesium (as magnesium citrate)	33 mg
Zinc (as zinc citrate)	6,7 mg
Vitamin B3 (as niacinamide)	3 mg
Vitamin B2 (as riboflavin)	2 mg
Vitamin A (as retinyl palmitate)	300 µg
Iodine (as potassium iodide)	50 µg
Selenium (as selenomethionine)	50 µg
Vitamin D (as cholecalciferol)	8,3 µg (1.U.)

**Inactive Ingredients:** Capsule (hydroxypropylmethylcellulose, magnesium stearate (vegetable) microcrystalline cellulose, and silica. **Sugar Free**  
**This product is suitable for vegetarians, gluten and dairy free.**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

THYROSOL offers a multifaceted approach by providing nutritional support for healthy thyroid function along with additional support for stress-related fatigue.

Ingredient	Uses for ingredient
Inositol (as myo-inositol)	Helps balance hormones and supports thyroid health, especially in PCOS
Rhodiola (Rhodiola rosea L.)	Reduces stress and supports adrenal function, benefiting thyroid regulation.
Vitamin E (as d-alpha-tocopheryl succinate)	Protects the thyroid from oxidative stress and supports thyroid function.
Magnesium (as magnesium citrate)	Supports hormone conversion (T4 to T3) and overall thyroid health.
Zinc (as zinc citrate)	Aids in thyroid hormone production and metabolism; deficiency impacts thyroid.
Vitamin B3 (as niacinamide)	Supports energy metabolism and thyroid hormone production.
Vitamin B2 (as riboflavin)	Aids in thyroid hormone conversion (T4 to T3).
Vitamin A (as retinyl palmitate)	Supports T4 to T3 conversion and healthy thyroid function.
Iodine (as potassium iodide)	Essential for thyroid hormone production.
Selenium (as selenomethionine)	Helps convert T4 to T3 and protects the thyroid from damage.
Vitamin D (as cholecalciferol)	Supports thyroid function and helps prevent deficiency-related issues.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take THYROSOL 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:** Stop taking THYROSOL at least two weeks before scheduled surgery. **Antibiotics:** Take your antibiotics 2 hours before or after taking THYROSOL. **Laboratory tests:** Active ingredients in THYROSOL may alter the results of tests. Please tell your healthcare practitioner that you are taking THYROSOL before having any laboratory tests.

#### 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**)

#### DOSE AND DIRECTIONS FOR USE

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

#### 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: Not recommended for people with bipolar disorder, high blood pressure, or those on antidepressants (SSRI, MAOI). High doses should be avoided in people with blood clotting disorders or on blood-thinning medications, kidney disease, heart block, or severe dehydration. People with copper deficiency, or those on immunosuppressants, liver disease, peptic ulcers, or gout, thyroid disorders, particularly hyperthyroidism or iodine sensitivity, high doses should be avoided in individuals with a history of skin cancer or prostate cancer, hypercalcemia, hyperparathyroidism, kidney disease, or active tuberculosis. If you are taking the following medication, please consult with your healthcare professional before taking: May interact with lithium, affecting its blood levels, antidepressants (SSRIs, SNRIs): Risk of serotonin syndrome when combined with Rhodiola, blood thinners (e.g., warfarin): Increases bleeding risk, calcium channel blockers: Increased risk of low blood pressure, antibiotics (e.g., tetracyclines), statins: Risk of muscle pain or damage, retinoid drugs: Increased risk of toxicity, thyroid medications: May interfere with thyroid hormone regulation, chemotherapy drugs: May alter the effectiveness of certain cancer treatments, thiazide diuretics: Increased risk of hypercalcemia. If any of the following happens, stop using THYROSOL 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 THYROSOL. 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.

These are all very serious effects. If you have them, you may have had a serious reaction to THYROSOL. 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 THYROSOL if you notice visible signs of deterioration.

#### IDENTIFICATION

Clear vegetable capsule with a light brown fill.

#### 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:

Amipro 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: 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## THYROSOL, 90 Kapsule

### SAMESTELING

**Elke een (1) kapsule van THYROSOL bevat die volgende aktiewe stowwe:**

Inositol (as myo-inositol)	200 mg
Rhodiola (Rhodiola rosea L.) [Risoomesttrak gestandaardiseer tot 1% (1,33 mg) salidroside en 3% (4,0 mg) rosavin's]	133 mg
Vitamiën E (as d-alfa-tokoferylsuksinaat)	44,7 mg
Magnesium (as magnesiumsitraat)	33 mg
Sink (as sinkstraat)	6,7 mg
Vitamiën B3 (as niacinamide)	3 mg
Vitamiën B2 (as riboflavin)	2 mg
Vitamiën A (as retinylpalmitaat)	300 µg
Jodium (as kaliumjodied)	50 µg
Selenium (as selenometionien)	50 µg
Vitamiën D (as cholecalciferol)	8,3 µg (333 IE)

**Onaktiewe bestanddele:** Kapsule (hidroksiopropylmetiëlsellulose), magnesiumstearaat (groente) mikrokristallyne sellulose en silika. **Suikervry** Hierdie produk is geskik vir vegetariërs, gluten- en suiwelvry.

### FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

THYROSOL bied 'n veelvlakkige benadering deur voedingsondersteuning te bied vir gesonde skildklierfunksie tesame met bykomende ondersteuning vir stresverwante moegheid.

Bestanddeel	Gebruik vir bestanddeel
Inositol (as myo-inositol)	Help om hormone te balanseer en ondersteun skildkliergesondheid, veral in PCOS
Rhodiola (Rhodiola rosea L.)	Verminder stres en ondersteun bynierfunksie, wat skildklierregulering bevoordeel.
Vitamiën E (as d-alfa-tokoferylsuksinaat)	Beskerms die skildklier teen oksidatiewe stres en ondersteun skildklierfunksie.
Magnesium (as magnesiumsitraat)	Ondersteun hormoonomsakeling (T4 tot T3) en algehele skildkliergesondheid.
Sink (as sinkstraat)	Hulpmiddels in skildklierhormoonproduksie en metabolisme; tekort beïnvloed skildklier.
Vitamiën B3 (as niacinamide)	Ondersteun energiemetabolisme en skildklierhormoonproduksie.
Vitamiën B2 (as riboflavin)	Vigs in tiroïedhormoon omsakeling (T4 tot T3).
Vitamiën A (as retinylpalmitaat)	Ondersteun T4 na T3 omsakeling en gesonde skildklierfunksie.
Jodium (as kaliumjodied)	Noodsaaklik vir skildklierhormoonproduksie.
Selenium (as selenometionien)	Help om T4 na T3 om te skakel en beskerm die skildklier teen skade.
Vitamiën D (as cholecalciferol)	Ondersteun skildklierfunksie en help om tekortverwante probleme te voorkom.

### KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **THYROSOL** 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:** Hou op om **THYROSOL** ten minste twee weke voor die geskeduleerde operasie te neem. **Antibiotika:** Neem jou antibiotika 2 ure voor of na die neem van **THYROSOL**. **Laboratoriumtoets:** Aktiewe bestanddele in **THYROSOL** kan die resultate van toets verander. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **THYROSOL** neem voordat jy enige laboratoriumtoets ondergaan.

### INTERAKSIES

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

**Volwassenes:** Neem een (1) kapsule, drie keer per dag saam met kos of soos voorgeskryf deur jou gesondheidspraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Nie aanbeveel vir mense met bipolêre verstoring, hoë bloeddruk, of diëgene op antidepressante (SSRI, MAO-r) nie, Hoë dosisse moet vermy word by mense met bloedstollingsversteurings of op bloedverdunde medikasie, Niersiekte, hartblok of ernstige dehidrasie, Mense met kopertekort, of diëgene op immuunonderdrukkers, lewersiekte, maagere of jig, skildklierafwykings, veral hipertireose of jodiumsensitiwiteit, hoë dosisse moet vermy word by individue met 'n geskiedenis van velkanker of prostaatkanker, hiperkalsemie, hiperparatiroïedisme, niersiekte of aktiewe tuberkulose.

As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Kan interaksie hê met litium, wat sy bloedvlakke beïnvloed, Anti-depressante (SSRI's, SNRI's): Risiko van serotoniensindroom wanneer dit gekombineer word met Rhodiola, Bloedverdunner (bv. warfarin): Verhoog bloedingsrisiko, Kalsiumkanaalblokkers: Verhoogde risiko van lae bloeddruk, Antibiotika (bv. tetrasielene), Stasiene: Risiko van spierpyn of skade, Retinoïedmiddels: Verhoogde risiko van toksisiteit, Skildkliermedikasie: Kan innemend met tiroïedhormoonregulering, Chemoterapiemiddels: Kan die doeltreffendheid van sekere kankerbehandelings verander, Tiazieddiuretika: Verhoogde risiko van hiperkalsemie. As enige van die volgende gebeur, hou op om **THYROSOL** te gebruik en vertel jou dokter of gaan na die ongevallende afdeling by jou naaste hospitaal:

- Allergiese reaksie- uitslag, Jiek / 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 **THYROSOL** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Hierdie effek is gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Naarheid / braking,

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **THYROSOL** 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 toets benodig.
- Jy moet 'n dokter raadpleeg indien jou afdeling verander 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 nuwe-effekte 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 nuwe-effekte.

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

### BERGING INSTRUKSIE

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

Beskerms 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 **THYROSOL** gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Maak groentekapsule skoon met 'n ligbruin vuisel.

### AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit doppie, induksiesêel, peuterkrimpseël, wattering 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 BESIGHEIDSADRES 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.

