

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### THYROSOL, 90 Capsules

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **THYROSOL** is available without a doctor's prescription.
- Nevertheless, you still need to use **THYROSOL** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **THYROSOL** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **THYROSOL** is and what it is used for.
- What you need to know before you take **THYROSOL**.
- How to take **THYROSOL**.
- Possible side effects.
- How to store **THYROSOL**.
- Contents of the pack and other information.

#### WHAT THYROSOL CONTAINS

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) rosinarin's]	133 mg
Vitamin E (as $\alpha$ -d-oligotocopheryl 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 (333 I.U.)

**Inactive ingredients:** Capsule (hydroxypropylmethylcellulose), magnesium stearate (vegetable) microcrystalline cellulose, and silica. **Sugar Free**

**This product is suitable for vegetarians, gluten and dairy free.**

#### WHAT THYROSOL IS AND WHAT IT IS USED FOR

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

#### BEFORE YOU TAKE THYROSOL

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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

#### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

#### TAKE OTHER MEDICINES WITH THYROSOL

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.

#### HOW TO TAKE THYROSOL

Do not share medicines prescribed for you with any other person. Always take **THYROSOL** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **THYROSOL** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **THYROSOL** may affect you.

#### 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.**



#### IF YOU TAKE MORE THYROSOL THAN YOU SHOULD

In the event of overdosage, consult your doctor, pharmacist.

Should none of these be available, contact the nearest hospital or poison control centre.

#### IF YOU FORGET TO TAKE THYROSOL

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**THYROSOL** may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **THYROSOL** 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 healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "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 **THYROSOL**.

#### STORAGE AND DISPOSING OF THYROSOL

Store all medicines out of the reach of children.

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original packaging.

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

Do not use **THYROSOL** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF THYROSOL

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

#### IDENTIFICATION OF THYROSOL

Clear vegetable capsule with a light brown fill.

#### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

**THIS LEAFLET WAS LAST REVISED ON**  
26 January 2025

#### NAME AND ADDRESS OF REGISTRATION HOLDER

**Distributed by:**  
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# PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## THYROSOL, 90 Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE

INLIGTING VIR U

- **THYROSOL** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **THYROSOL** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **THYROSOL** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

**WAT IS IN HIERDIE INLIGTINGSBLAD**

- Wat **THYROSOL** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **THYROSOL** neem.
- Hoe om **THYROSOL** te neem.
- Moontlike nuwe-effekte.
- Hoe om **THYROSOL** te bêre.
- Inhoud van die pak en ander inligting

**WATER THYROSOL BEVAT**

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

Inositol (as myo-inositol)	200 mg
Rhodiola (Rhodiola rosea L.) [Risoomekstrak 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 selenomietionien)	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.**

**WAT IS THYROSOL KAPSULES EN WAARVOOR WORD DIT GEBRUIK**

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

**VOORDAT JY THYROSOL NEEM**

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

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

**BESTUUR EN GEBRUIK VAN MASJIENE**

Dit is nie altyd moontlik om te voorspel in watter mate **THYROSOL** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **THYROSOL** jou beïnvloed.

**NEEM VAN ANDER MEDISYNE SAAM MET THYROSOL**

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

**SWANGERSKAP EN BORSVOEDING**

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanulling neem.

**HOE OM THYROSOL TE NEEM**

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **THYROSOL** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

**Aanwysings vir gebruik:**

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

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

**AS JY MEER THYROSOL NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGEET OM THYROSOL TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

**MOONTLIKE NUWE-EFFEKTE**

**THYROSOL** kan nuwe-effekte hê.

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Nie doodruk, of diegene op antidepressante (SSRI, MAO-r) nie, Hoë dosisse moet vermy word by mense met bipolêre versteuring, hoë bloeddruk, of diegene op antidepressante (SSRI, MAO-r) nie, Hoë dosisse moet vermy word by mense met bloedstollingsversteurings of op bloedverdundende medikasie, Niersiekte, hartbolk of ernstige dehidrasie, Mense met koptekort, of diegene op immuunonderdrukkers, lewersiekte, maagere of jig, skildklierafwykings, veral hipertiese of jodiumsensitiwiteit, hoë dosisse moet vermy word by individue met 'n geskiedenis van velkanker of prostaatkanker, hiperkalsemie, hiperparatiroidisme, niersiekte of aktiewe tuberkulose. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Kan interaksie hê met litium, wat sy bloedvlakke beïnvloed, Antidepressante (SSRI's, SNRI's): Risiko van serotoniensindroom wanneer dit gekombineer word met Rhodiola, Bloedverdunder (bv. warfarin): Verhoogde bloedingsrisiko, Kalsiumkanaalblokkers: Verhoogde risiko van lae bloeddruk, Antibiotika (bv. tetrasielene), Statiene: Risiko van spierpyn of skade, Retinoïedmiddels: Verhoogde risiko van toksisiteit, Skildkliermedikasie: Kan inmeng met tiroïedhormoonregulerende, Chemoterapiemiddels: Kan die doeltreffendheid van sekere kankerbehandelings verander, Tiazieddiuretika: Verhoogde risiko van hiperkalsemie. As enige van die volgende gebruek, hou op om **THYROSOL** te gebruik en vertel jou dokter of gaan na die ongevallenafdeling 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 **THYROSOL** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisyn as dit voortduur):

- naarheid / braking.

Nie alle nuwe-effekte en interaksies wat vir **THYROSOL** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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.

**AANMELDING VAN NUWE-EFFEKTE**

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **THYROSOL**.

**HOE OM THYROSOL TE BÊRE**

Bêre alle medisyne buite bereik van kinders.

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

Beskermer teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

**AANBIEDING VAN THYROSOL**

'n Wit 250 ml HDPE-bottel met 'n wit doppie, induksiesieël, peuterkrimpiesieël, wattering en silikagetsakkie.

**IDENTIFIKASIE VAN THYROSOL**

Duidelike groentekapsule met 'n ligbruin vulsel.

**REGISTRASIE NOMMER**

Om deur SAHPRA teogeken te word by registrasie.

**TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING**

Skandeer QR-code.

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

26 Januarie 2025

**NAAM EN ADRES VAN REGISTRASIEHOUER**

Versprei deur:

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