PROFESSIONAL INFORMATION
NATIVA COMPLEX® THYROID SUPPORT capsules
• Complementary Medicine.
• D.33.7 Complementary Medicines: Discipline-Specific Traditional Claims – Combination Product
• This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
NATIVA COMPLEX® THYROID SUPPORT (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

Active Ingredients	Per capsule	Per maximum daily dose (2 capsules)	% NRV[#] per maximum daily dose (2 capsules)
Ascophyllum nodosum (knotted wrack/ Norwegian kelp) [herb powder]	100 mg	200 mg	*
L-tyrosine	250 mg	500 mg	*
Nicotinamide (Vitamin B3)	9 mg	18 mg	113 %
Calcium-D pantothenate (Vitamin B5)	6 mg	12 mg	240 %
Pyridoxine hydrochloride (Vitamin B6)	2 mg	4 mg	235 %
Riboflavin (Vitamin B2)	1,6 mg	3,2 mg	246 %
Thiamine hydrochloride (Vitamin B1)	1,4 mg	2,8 mg	233 %
Selenium AAC** providing Selenium (elemental)	2 mg 40 µg	4 mg 80 µg	146 %
Cyanocobalamin (Vitamin B12)	1 µg	2 µg	83 %

[#]Nutrient reference values for adults and children older than 4 years.
*NRV not established.
**Amino Acid Chelate.
Nativa Complex® Thyroid Support is sugar free.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Capsule, gelatine hard.
Nativa Complex® Thyroid Support capsules are light pink.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Nativa Complex® Thyroid Support is a supplement intended to support the function of the thyroid. It can support the body to counter symptoms of fatigue and an underactive thyroid.
Efficacy of support may vary between users.
4.2 Posology and method of administration
The recommended daily dosage is
Adults 18 years and older:
One (1) capsule in the morning and one (1) capsule in the evening with a glass of water, after a meal.
Advise the patient to take a two to four week break after 3 months of continuous use before restarting (see **4.4**).
4.3 Contraindications
• Must not be given to patients with known hypersensitivity or allergy towards iodine or any of the ingredients of Nativa Complex® Thyroid Support (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
• Must not be given to patients with hyperthyroidism as L-tyrosine and kelp supplementation can aggravate the condition.
• Must not be given to patients suffering from liver disease or have peptic ulcer disease as Nativa Complex® Thyroid Support contains nicotinamide.
• Must not be given to patients known to have cobalamin or cobalt hypersensitivity as Nativa Complex® Thyroid Support contains vitamin B12.
• Patients taking any chronic medication should not use this product without consulting their medical practitioner.
4.4 Special warnings and precautions for use
• Patients with a history of non-melanoma skin cancer should use this product with caution as Nativa Complex® Thyroid Support contains selenium.
• Patients with bleeding disorders or taking anticoagulants/blood thinners or anti-platelet medication should use this product with caution as Nativa Complex® Thyroid Support contains kelp and L-tyrosine (see **4.5**).
• Advise the patient to take a two to four week break after 3 months of continuous use before restarting as Nativa Complex® Thyroid Support contains L-tyrosine.
• Do not exceed the daily recommended dose.
• Do not use after the date of expiry.
• Products containing herbal ingredients may interact with some medication.
Porphyria
Safety has not been established.
4.5 Interaction with other medicinal products and other forms of interactions
No interaction studies have been performed on Nativa Complex® Thyroid Support capsules, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Vitamin B3 and selenium	Blood thinners (anticoagulant or anti-platelet medication) e.g. warfarin	May have a blood thinning effect increasing the risk of bleeding.
L-tyrosine	Thyroid hormones	Tyrosine is a precursor to thyroxine and may increase levels of thyroid hormones.
L-tyrosine	Levodopa	May decrease the effectiveness of levodopa.
L-tyrosine	Monoamine oxidase inhibitors (MOAIs)	MAOIs can potentiate sympathomimetic substances (adrenergic medication /amines) and related compounds to induce a hypertensive crisis with potential risk of heart attack or stroke.

4.6 Fertility, pregnancy and lactation
Pregnancy
Use during pregnancy is not recommended as safety during pregnancy has not been established.
Breastfeeding
Use is not recommended as safety during lactation has not been established.
Fertility
There are no known effects of Nativa Complex® Thyroid Support capsules on fertility.
4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Nativa Complex® Thyroid Support capsules should not affect the ability to drive or operate machinery.
4.8 Undesirable effects
Nativa Complex® Thyroid Support capsules are generally well tolerated with the occurrence of adverse events unknown.
Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.
Adverse reactions reported in the literature are listed below, by system organ class and frequency. Frequencies are defined as:
• very common (≥1/10)
• common (≥1/100 to <1/10)
• uncommon (≥1/1,000 to <1/100)
• rare (≥1/10,000 to 1</1,000)
• very rare (<1/10,000)
• not known (cannot be estimated from the available data)

Adverse events table		
System Organ Class	**Frequency**	**Adverse Event**
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria and itching.
Gastrointestinal disorders	Not known	Abdominal discomfort, diarrhoea, difficulty swallowing, heartburn, nausea and vomiting.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (skin rash and itching) and alopecia.
Musculoskeletal and connective tissue disorders	Not known	Arthralgia (joint pain).

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.
Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product 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://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
4.9 Overdose
Symptoms
See **4.8 Undesirable effects**
In overdose, side effects can be precipitated and/or be increased.
There is no evidence that this product can lead to an overdose when used as recommended.
Treatment
If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D.33.7 Complementary Medicines: Discipline-Specific Traditional Claims – Combination product
Pharmacotherapeutic classification: Vitamins and other combinations
ATC code: A11JC
Ascophyllum nodusum (Knotted wrack/ Norwegian kelp)
Ascophyllum nodosum is high in polysaccharides such as fucoidans, ascophyllan, laminarin, mannitol, alginate and phlorotannins. It also contains vitamins and minerals such as iodine and has been shown to inhibit the production of pro-inflammatory cytokines.
L-tyrosine
L-tyrosine is a nonessential amino acid that the body synthesizes from phenylalanine. It is a precursor for the synthesis of catecholamines, norepinephrine, epinephrine, and dopamine and may play a role in depression. It is also a precursor for thyroxine and melanin.
Vitamin B1
Thiamine functions as a coenzyme in more than 24 enzymes, most importantly pyruvate dehydrogenase, transketolase and 2-oxo-glucaratedehydrogenase. Thiamine is crucial in glucose energy-utilizing pathways.
Vitamin B2
Riboflavin and its active coenzymes function as hydrogen carriers in oxidation-reduction reactions. Riboflavin is needed for processes involved with activity of the adrenal gland, activation of vitamin B6, creation of niacin, formation of red blood cells, and maintenance of erythrocyte integrity.
Vitamin B3
Nicotinamide acts as an antioxidant by preventing adenine dinucleotide (NAD) depletion during DNA repair when inhibiting poly (ADP-ribose) polymerase (PARP). It also decreases inflammation by modulating interleukin-1-exposedchondrocytes.
Vitamin B5
Pantothenic acid is needed for intermediary metabolism of lipids, carbohydrates, and proteins. Pantothenic acid is a precursor of coenzyme A (CoA), which is required in the synthesis and degradation of multiple compounds.
Vitamin B6
Vitamin B6 is involved in carbohydrate and lipid metabolism and required for amino acid metabolism. In the body, vitamin B6 is converted to the coenzyme pyridoxal phosphate for a wide variety of metabolic reactions.
Vitamin B12
Vitamin B12 is required for myelin and nucleoprotein synthesis, normal erythropoiesis, normal growth, and cell reproduction. Vitamin B12 is involved in conserving sulfhydryl groups in the reduced form required by enzymes involved in carbohydrate and fat metabolism and protein synthesis.
Selenium
Selenium is a major component of the glutathione peroxidase enzyme system. This system protects intracellular structures from oxidative damage.
5.2 Pharmacokinetic properties
Ascophyllum nodusum (knotted wrack/ Norwegian kelp)
Absorption: Phlorotannins and phlorotannin metabolites are detectable in plasma. Iodine levels are also increased after taking Ascophyllum nodosum powder but is not absorbed as well as with potassium iodide supplementation.
Metabolism: Phlorotannins are conjugated as glucuronides and/or sulfates. The majority of phlorotannin metabolites are detected in plasma between 6 and 24 hours after intake, this suggests metabolism by gut microbes occurs in the large intestine prior to absorption.
Excretion: Conjugated and unconjugated phlorotannins are excreted in the urine between 8 and 24 hours after taking *Ascophyllum nodosum*. Iodine absorbed from *Ascophyllum nodosum* powder is excreted in the urine.
L-tyrosine
Absorption: L-tyrosine levels are increased in the blood in a dose-dependent manner following oral use. Peak plasma levels of tyrosine generally occur within 1,5 to 3 hours after oral intake, however reaching maximum plasma concentration may take as long as 6 hours.
Metabolism: In the brain, L-tyrosine is converted to L-3,4-dihydroxyphenylalanine (L-dopa), dopamine, norepinephrine, and then epinephrine.
Distribution: L-tyrosine is transported across the blood brain barrier by the large neutral amino acid (LNAA) transporter and competes with other LNAAs, such as tryptophan, to get into the brain.
Excretion: Intake of tyrosine increases urinary levels of norepinephrine, epinephrine, dopamine, 3-methoxy-4-hydroxyphenylglycol, vanillylmandelic acid, and homovanillic acid in men.
Vitamins and minerals
A sufficient intake of vitamins and minerals is necessary to maintain normal energy metabolism, and physiological function. Unbalanced diet and insufficient dietary intake of vitamins and minerals can result in subnormal health.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Magnesium stearate
Gelatine capsule (capsule constituents: bovine gelatine, colorants, titanium dioxide)
Colloidal silicon dioxide
Tapioca starch
6.2 Incompatibilities
None known
6.3 Shelf life
24 months
6.4 Special precautions for storage
• Store in a dry place at or below 25 °C.
• Protect from light and moisture.
• Keep in original packaging until required for use.
6.5 Nature and contents of container
Nativa Complex® Thyroid Support capsules are light pink.
Nativa Complex® Thyroid Support capsules are available in a white high density polyethylene plastic container with a pink flip-top cap. It contains 60 capsules and includes a patient information leaflet in a printed unit carton.
6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa
Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za

8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated

10. DATE OF REVISION OF THE TEXT
September 2022

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