

PROFESSIONAL INFORMATION

Releaf Theanine



SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

Releaf Theanine (tablets).

COMPOSITION:

Each tablet contains:

L-Theanine 250 mg

Inactive ingredients: Calcium carbonate, colloidal silicon dioxide, magnesium stearate, povidone, sodium starch glycolate.

Contains sugar (110 mg alpha-lactose monohydrate).

CATEGORY AND CLASS:

Category of medicine: D

Class: D 34.1 Amino Acids

Complementary Medicine: Health Supplement.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Releaf Theanine contains an amino acid, L-Theanine, which is naturally found in tea plants.

L-Theanine: A natural amino acid that helps to support and temporarily promote relaxation.

It supports the maintenance of healthy sleep and acts as a caffeine antagonist.

Pharmacokinetic properties:

The active ingredient in this formulation is well known. Pharmacokinetic studies have not been conducted on **Releaf Theanine**.

INDICATIONS:

Releaf Theanine is a product of natural origin used to assist and temporarily promote relaxation. It also helps with the maintenance of healthy sleep and acts as a caffeine antagonist.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Not recommended during pregnancy and/or lactation.

Contraindicated in patients with hypotension.

Contraindicated in combination with antihypertensive medicines.

WARNINGS and SPECIAL PRECAUTIONS:

L-Theanine may have a hypotensive effect.

Contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **Releaf Theanine**.

Effects on the ability to drive and use machines:

No studies on the effect of **Releaf Theanine** on the ability to drive or operate machines were performed. However, L-Theanine might have a hypotensive effect, which could affect the ability to drive or operate machines. Patients should not drive or operate machinery until it is established that their ability to perform such activities has not been affected.

INTERACTIONS:

Adverse effects have not become known with the simultaneous ingestion of **Releaf Theanine** and food or drink.

Research has shown that L-Theanine can have a hypotensive effect. **Releaf Theanine** should be used with caution in combination with other herbs or medicines with hypotensive effects, as this might increase the risk of hypotension. These herbs and medicines include andrographis, casein peptides, cat's claw, coenzyme Q10, fish oil, L-arginine, lycium and stinging nettle.

Releaf Theanine should also be used with caution in combination with antihypertensive medicines, as L-Theanine could enhance the effects of these treatments. These herbs and medicines include captopril, enalapril, losartan, valsartan, diltiazem, amlodipine, hydrochlorothiazide and furosemide.

L-Theanine may inhibit the stimulant effects of caffeine and may reduce the effects of caffeine and caffeine-containing herbs and medicines. Therefore, **Releaf Theanine** will reduce the effects of coffee, black tea, oolong tea, guarana, mate and cola.

Concomitant use of L-Theanine with stimulant medicines might decrease the effects of these treatments. Avoid using **Releaf Theanine** in combination with these medicines such as diethylpropion, epinephrine, phentermine and pseudoephedrine.

HUMAN REPRODUCTION:

Pregnancy and lactation:

Not recommended for use in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

Adults: Take 1 tablet daily.

Take with a glass of water, when required:

- during the day to reduce restlessness and/or anxiety or,
- at bedtime to support the maintenance of healthy sleep.

If the symptoms worsen or persist, please consult your healthcare practitioner.

SIDE EFFECTS:

No known side effects.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No known symptoms of overdosage.

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:

A flat round white tablet with a bevelled edge and breakline.

PRESENTATION:

20's: The tablets are available in PVC/aluminium blister strips, with each blister strip containing 10 tablets.

Each carton contains 2 blister strips.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.

Do not remove the blisters from the original packing until required for use.

Do not use later than the expiry. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

Releaf Theanine has not been evaluated by the SAHPRA for its quality, safety or intended use. **Releaf Theanine** does not intend to prevent or cure any form of illness or disease, and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

RELEAF PHARMACEUTICALS (PTY) LTD

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DATE OF PUBLICATION:

February 2018.

RP0034/17A

PATIENT INFORMATION LEAFLET

This leaflet tells you about **Releaf Theanine**.

Health Supplement

SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

Releaf Theanine (tablets).

Read all of this leaflet carefully because it contains important information for you. **Releaf Theanine** is available without a doctor's prescription. Nevertheless, you still need to use **Releaf Theanine** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.
Do not share **Releaf Theanine** with any other person.
Ask your pharmacist if you need more information or advice.
You must see a doctor if your symptoms worsen or do not improve.

WHAT Releaf Theanine CONTAINS:

Each tablet contains:

Active substances are:

L-Theanine 250 mg

The other ingredients are calcium carbonate, colloidal silicon dioxide, magnesium stearate, povidone sodium starch glycolate.

Contains sugar (110 mg alpha-lactose monohydrate).

WHAT Releaf Theanine IS USED FOR:

Releaf Theanine is a product of natural origin used to assist and temporarily promote relaxation. It also helps with the maintenance of healthy sleep and acts as a caffeine antagonist (in other words, it acts to counteract the effects of caffeine).

BEFORE YOU TAKE Releaf Theanine:

Do NOT take Releaf Theanine:

- If you are allergic to any of the ingredients.
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding") (see "HOW TO TAKE Releaf Theanine").

Take special care with Releaf Theanine:

L-Theanine can lower blood pressure.

Releaf Theanine does not intend to prevent or cure any form of illness or disease, and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Keep away from children. Do not exceed the recommended dose.

Please consult your doctor or pharmacist prior to use if you:

- have low blood pressure.
- are being treated for high blood pressure.

Releaf Theanine with food and drink:

There are no known side effects to taking **Releaf Theanine** with food and drink.

Pregnancy and breastfeeding:

Do not use **Releaf Theanine** during pregnancy or while you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

No studies on the effect on the ability to drive or use machines have been performed. However, L-Theanine may cause a lowering in blood pressure, which might affect the ability to drive or use machines. Patients should not drive or operate machinery until it is established that their ability to perform such activities has not been affected.

Important information about some of the ingredients of Releaf Theanine:

Releaf Theanine contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **Releaf Theanine**.

Taking other medicines with Releaf Theanine:

Allways tell your healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. The use of **Releaf Theanine** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Do not take **Releaf Theanine** in combination with medicines such as:

- other herbs or medicines with hypotensive effects, such as andrographis, casein peptides, cat's claw, coenzyme Q10, fish oil, L-arginine, lycium and stinging nettle.
- antihypertensive medicines, such as captopril, enalapril, losartan, valsartan, diltiazem, amlodipine, hydrochlorothiazide, and furosemide.

- caffeine and caffeine-containing herbs and medicines such as coffee, black tea, oolong tea, guarana, mate and cola.

HOW TO TAKE Releaf Theanine:

The usual dose is:

Adults: Take 1 tablet daily.

Take with a glass of water, when required:

- during the day to reduce restlessness and/or anxiety or,
- at bedtime to support the maintenance of a healthy sleep.

If the symptoms worsen or persist, please consult your healthcare practitioner.

If you take more Releaf Theanine than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control center.

If you forget to take Releaf Theanine:

Always take **Releaf Theanine** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule (see "HOW TO TAKE **Releaf Theanine**"). Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

Releaf Theanine can have side effects.

Not all side effects reported for **Releaf Theanine** are included in this leaflet. Should your general health worsen while taking **Releaf Theanine**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Releaf Theanine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- No known side effects

Please report/ inform your doctor or pharmacist if you notice any side-effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF Releaf Theanine:

Store in a cool, dry place at or below 25 °C.

Do not remove the blisters from the original packing until required for use.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label. Return all unused **Releaf Theanine** to your pharmacist.

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

PRESENTATION OF Releaf Theanine:

Releaf Theanine are available in PVC/aluminium blister strips, with each blister strip containing 10 tablets.

Each carton of 20 tablets contains 2 blister strips.

IDENTIFICATION OF Releaf Theanine:

A flat round white tablet with a bevelled edge and breakline.

REGISTRATION NUMBER:

To be allocated.

Releaf Theanine has not been evaluated by the SAHPRA for its quality, safety or intended use.

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

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PASIËNTINLIGTINGSBLAD

Inligting oor **Releaf Theanine**.

Gesondheidsaanvulling

SKEDULERINGSSTATUS: **S0**

EIENDOMSNAAM EN DOSEERVORM:

Releaf Theanine (tablette).

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting. **Releaf Theanine** is beskikbaar sonder 'n dokter se voorskrif. U moet egter steeds **Releaf Theanine** versigtig gebruik om die beste resultate daarmee te verkry.

Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
Moenie **Releaf Theanine** met enige ander persoon deel nie.
Indien u verdere inligting of advies verlang, vra asseblief u apteker.
U moet 'n dokter raadpleeg indien u simptome vererger.

WAT Releaf Theanine BEVAT:

Elke tablet bevat:

Aktiewe bestanddele is:

L-Teaniën 250 mg

Die ander bestanddele is kalsiumkarbonaat, kolloïdale silikondioksied, magnesiumstearaat, natrium-styselglukolaat, povidoon.

Bevat suiker (110 mg alfa-laktose monohidraat).

WAARVOOR Releaf Theanine GEBRUIK WORD:

Releaf Theanine is 'n produk van natuurlike oorsprong wat gebruik word om ontspanning te ondersteun en tydelik te bevorder. Dit ondersteun ook gesonde slaap en tree op as 'n kaffeïen antagonist (met ander woorde, dit help om die effekte van kaffeïen teen te werk).

VOORDAT U Releaf Theanine NEEM:

Moet NIE Releaf Theanine NEEM NIE:

- Indien u allergies is vir enige van die bestanddele.
- Indien u swanger is of u baba borsvoed (sien "Swangerskap en borsvoeding") (sien "HOE OM **Releaf Theanine** TE GEBRUIK").

Neem spesiale sorg met Releaf Theanine:

L-Teaniën kan bloeddruk verlaag.

Releaf Theanine beoog nie om enige ongesteldheid of siektetoestand te genees nie en moet nie enige medikasie vervang nie. Mense wat aan 'n chroniese mediese toestand ly moet hulle gesondheidspraktisyn raadpleeg voor hulle hierdie produk gebruik. Hou buite bereik van kinders. Moenie die voorgeskrewe dosis oorskry nie.

Raadpleeg asseblief u dokter of apteker voor gebruik indien u:

- lae bloeddruk het.
- behandel word vir hoë bloeddruk.

Die neem van Releaf Theanine met kos en drinkgoed:

Daar is geen bekende nuwe-effekte om **Releaf Theanine** saam met kos en drinkgoed te neem nie.

Swangerskap en borsvoeding:

Moenie **Releaf Theanine** neem terwyl u swanger is of u baba borsvoed nie.

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker voor u hierdie medisyne neem.

Bestuur en die gebruik van masjinerie:

Geen navorsingstudies is uitgevoer oor die effek van **Releaf Theanine** op die vermoë om te bestuur of masjinerie te hanteer nie. L-Teaniën kan egter 'n hipotensiewe effek hê, wat die vermoë om te bestuur kan beïnvloed. Pasiënte moet hulle daarvan weerhou om te bestuur en masjinerie hanteer totdat daar vasgestel kon word dat hulle vermoë om hierdie aktiwiteite te beoefen nie beïnvloed word nie.

Belangrike informasie oor sommige van die bestanddele in Releaf Theanine:

Releaf Theanine bevat laktose. Pasiënte met die seldsame oorerflike kondisies van laktose/fruktose of galaktose intoleransies moenie **Releaf Theanine** gebruik nie.

Die neem van ander medisyne saam met Releaf Theanine:

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne. Die gebruik van **Releaf Theanine** saam met hierdie medisyne mag ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Moenie **Releaf Theanine** in kombinasie met medisyne soos die volgende gebruik nie:

- ander kruie of medisyne met hipotensiewe effekte soos andrographis, kaseien peptiede, kattelouranker, koënsiem Q10, visolie, L-arginien, lycium en brandnetel.
- antihipertensiewe medisyne, soos kaptopriel, enalapriel, losartan, valsartan, diltiasem, amlodipien, hidrochloortiasied en furosemied.
- kaffeïen en kaffeïenbevattende kruie soos koffie, swart tee, oolong tee, guarana, mate en kola.

HOE OM Releaf Theanine TE GEBRUIK:

Die gewone dosis is:

Volwassenes: Neem 1 tablet daaglik.

Neem met 'n glas water soos benodig:

- gedurende die dag om rusteloosheid en of angs te verlig of,
- voor slaapenstyd om gesonde slaap te handhaaf.

As die simptome vererger of voortduur, raadpleeg 'n gesondheidsorgpraktisyn.

Indien u meer Releaf Theanine geneem het as wat u moes:

In die geval van 'n oordosis, raadpleeg u dokter of apteker. As geeneen van hulle beskikbaar is nie, soek onmiddellik hulp by die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om Releaf Theanine te neem:

Neem **Releaf Theanine** altyd soos voorgeskryf. Indien u 'n dosis vergeet het, neem dit so gou as wat u onthou. Indien u egter nie van die vergete dosis onthou voordat dit tyd is vir die volgende dosis nie, slaan die vergete dosis oor en keer terug na u gewone doseringskedule (sien "HOE OM **Releaf Theanine** TE GEBRUIK"). Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

MOONTLIKE NUWE-EFFEKTE:

Releaf Theanine kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir **Releaf Theanine** gemeld is, is in hierdie inligtingstuk vervat nie. Indien u algemene gesondheid agteruitgaan terwyl u **Releaf Theanine** gebruik, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Releaf Theanine kan die volgende nuwe-effekte hê:

- Geen nadelige nuwe-effekte is bekend nie.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

BERGING EN WEGDOEN VAN Releaf Theanine:

Bewaar in 'n koel, droë plek by of benede 25 °C.

Moenie die stolpverpakings uit die oorspronklike verpakings verwyder totdat dit nodig is vir gebruik nie.

Beskerm teen lig.

HOU BUITE BEREIK VAN KINDERS.

Moenie gebruik na die vervaldatum op die etiket nie. Neem alle ongebruikte **Releaf Theanine** na u apteker terug.

Moenie ongebruikte **Releaf Theanine** in afvoerpype of rioolsisteme, byvoorbeeld toilette weggooi nie.

AANBIEDING VAN Releaf Theanine:

Releaf Theanine is beskikbaar in PVC/aluminium stolpverpakking, met elke stolpverpakking wat 10 tablette bevat. Elke dosie van 20 tablette bevat 2 stolpverpakings.

IDENTIFIKASIE VAN Releaf Theanine:

'n Ronde plat wit tablet met 'n skuins rant en 'n halveerlyn.

REGISTRASIENOMMER:

Sal toegeken word.

Releaf Theanine is nie deur die Sahpra geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN SAKEADRES VAN DIE HOUER VAN DIE REGISTRASIE:

RELEAF PHARMACEUTICALS (EDMS) BPK

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