

PROPRIETARY NAME AND DOSAGE FORM:

CALM
KIDS GUMMIES (60)

DISCLAIMER: This medicine has not been evaluated by SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure, or prevent any disease.

SCHEDULING STATUS: Unscheduled

COMPOSITION: Each 2 gummies contains:

Ingredients	Elemental value	*NRV
L-Theanine	100 mg	-
Valerian Extract 4:1 - Valeriana officinalis L.. (Parts: Root)	15 mg	-
Chamomile Extract Anthemis Nobilis (LINN.)	15 mg	-
* South African Nutrient reference values for individuals 4 years and older - not established		

Other Ingredients: Glucose syrup, sucrose, purified water, gelatine (bovine), citric acid, flavourant, sodium citrate, colourant. Contains no artificial sweetener. Contains sugar: glucose (1 g), sugar (0.75g)

Gelatine is Halal certified at source.

PHARMACOLOGICAL CLASSIFICATION:

34. 13 Category D (Health Supplement) [S0]

PHARMACOLOGICAL ACTION: Health supplement.

INDICATIONS: Indicated as a supplement where poor dietary intake of the listed active ingredients exist.

CONTRA-INDICATIONS:

- Hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

- Large doses may give rise to digestive discomfort and may lead to excessive drowsiness.

INTERACTIONS:

No known interactions with existing conditions at recommended dose.

Medicines that might interact with these gummies are:

- Sedative Medications: Valerian extract may enhance the sedative effects of these medications, leading to excessive drowsiness and dizziness.
- Benzodiazepines: Valerian extract can potentiate the effects of these medications, leading to increased sedation.

DOSAGE AND DIRECTIONS FOR USE:

The recommended usage is:

Children ages 3-12: Take 2 gummies daily as needed.

Do not exceed the recommended dose. This product should not be used as a substitute for a balanced diet.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

This supplement should be used with caution in individuals with the following medical conditions:

- Individuals with known allergies to plants in the Asteraceae family, which includes chamomile, should use

this product with caution, as it may cause allergic reactions.

- Depression: Valerian extract may worsen symptoms of depression.
- Liver Disorders: Valerian extract should be used cautiously in individuals with liver conditions.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In case of an accidental overdose, discontinue use and seek medical professional assistance immediately. Treatment is symptomatic and supportive.

Symptoms overdose may include:

- nausea, vomiting, excessive drowsiness, and gastrointestinal discomfort.

IDENTIFICATION:

Purple, dome shaped gummy with a grape flavour.

PRESENTATION:

Clear jar with green lid, packaged with tamperproof induction seal, labelled with clear, detailed information printed on the label. Containing 60 gummies.

STORAGE INSTRUCTIONS:

Store in a cool, dry place below 25 °C. Do not leave container open.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

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

Vitatech

Physical address: Cnr Parkin & Delson Street

North End, Gqeberha, 6001, South Africa.

Tel: 041 816 3100

Email: ask@vitatechhealth.com

Website: www.vitatechhealth.com

DATE OF PUBLICATION OF THE PACKAGE INSERT:

July 2023

HANDELSNAAM EN DOSERINGSVORM:

CALM
KIDS GUMMIES (60)

VRYWARING: Hierdie medisyne is nie deur SAHPRA geëvalueer ten opsigte van die kwaliteit, veiligheid of beoogde gebruik daarvan nie. Hierdie medisyne is nie bedoel vir die diagnosering, behandeling, genesing of voorkoming van enige siekte nie.

SKEDULERINGSTATUS: Ongeskeduleerd

SAMESTELLING: Elke 2 gummies bevat:

Bestanddele	Elementeel waarde	*NRV
L-Theanien	100 mg	-
Valeriaan Ekstrak 4:1 - Valeriana officinalis L.. (Dele: Wortel)	15 mg	-
Kamille Ekstrak Anthemis Nobilis (LINN.)	15 mg	-
* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer - nie vagestel nie		

Ander bestanddele is: Glukosestroop, suikrose, gesuiwerde water, gelatien (bees), sitroensuur, geur, natriumsitraat, kleurstof. Bevat geen kunsmatige versoeter. Bevat suiker: glukose (1g), suiker (0.75g)

Gelatien is Halal gesertifiseer by die bron.

FARMAKOLOGIESE KLASSEFIKASIE:

34.13 Kategorie D (Gesondheidsaanvuller) [S0]

FARMAKOLOGIESE WERKING: Gesondheidsaanvuller

INDIKASIES: Aangedui as 'n aanvulling waar swak dieetiname van die genoemde aktiewe bestanddele voorkom.

KONTRA-LNDIKASIES:

- Hipersensitiwiteit vir enige van die bestandele.

WAASKUWINGS EN SPESIALE VOORSORGMATREËLS:

- Groot dosisse mag lei tot maag ongemak en kan tot buitensporige slaperigheid lei.

INTERAKSIES:

Geen bekende interaksies teen die aanbevole dosis.

Medisyne wat kan interaksie hê met die gummies is:

- Sedatiewe Medikasie: Valeriaanekstrak kan die sederende effekte van hierdie medikasie versterk, wat tot buitensporige dowwarnigheid en duiseligheid kan lei.
- Benzodiazepiene: Valeriaanekstrak kan die effekte van hierdie medikasie versterk, wat tot verhoogde sedasie kan lei.

DOSIS EN GEBRUIKSAANWYSINGS:

Die aanbevole gebruik is:

Ouderdom 3-12: Neem daaglik 2 gelletjies soos nodig.

Moenie die aanbevole dosis oorskry nie. Die produk moenie ‘n gebalanseerde dieet vervang nie.

MOONTLIKE NEWE-EFFEKTE EN SPESIALE VOORBERGING:

Hierdie aanvulling moet met versigtigheid gebruik word by individue met die volgende mediese toestande:

- Individue met bekende allergieë vir plante in die Asteraceae-familie, wat kamille insluit, moet hierdie

produk met omsigtigheid gebruik, omdat dit allergiese reaksies kan veroorsaak.

- Depressie: Valeriaan-uittreksel kan simptome van depressie vererger.
- Leerstoornisse: Valeriaan-uittreksel moet met omsigtigheid gebruik word by individue met leeraandoenings.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

In geval van 'n toevallige oordosis, staak die gebruik en soek onmiddellik mediese hulp. Behandeling is simptome en ondersteunend.

Simptome van 'n oordosis kan insluit:

- nausea, braking, oormatige sluimerigheid, en gastro-intestinale ongemak.

IDENTIFIKASIE:

Pers, koepelvormige gummy met n druif geur.

AANBIEDING: Deurskynende bottle met groen deksel, en 'n peuterbestande induksie-seël. 'n Gedrukte etiket met volledige aanwysings is op die houer aangebring. Bevat 60 gummies.

BERGINGSAANWYSINGS:

Bêre op 'n koel, droë plek onder 25 °C. Moenie die houer oop laat. HOU BUITE BEREIK VAN KINDERS

REGISTRASIE NOMMER:

Word ge-allokeer.

NAAM EN BESIGHEIDS ADRES VAN DIE APPLIKANT:

Vitatech

Adress: Cnr Parkin & Delson Street

North End, Gqeberha, 6001, Suid Afrika.

Tel: 041 816 3100

E-pos: ask@vitatechhealth.com

Webwerf: www.vitatechhealth.com

DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET:

Julie 2023

PROPRIETARY NAME AND DOSAGE FORM:

CALM KIDS GUMMIES (60)

DISCLAIMER: This medicine has not been evaluated by SAPHRA. This medicine is not intended to diagnose, treat, cure, or prevent any disease.

Read all this leaflet carefully because it contains important information for you. This medicine is available without a doctor's prescription, for you to use as a vitamin supplement. Nevertheless, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must go see a doctor if you experience worrying symptoms.

SCHEDULING STATUS: Unscheduled

COMPOSITION: Each 2 gummies contains:

Ingredients	Elemental value	*NRV
L-Theanine	100 mg	-
Valerian Extract 4:1 - Valeriana officinalis L.. (Parts: Root)	15 mg	-
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Other Ingredients: Glucose syrup, sucrose, purified water, gelatine (bovine), citric acid, flavourant, sodium citrate, colourant. Contains no artificial sweetener. Contains sugar: glucose (1 g), sugar (0.75g) **Gelatine is Halal certified at source.**

WHAT IS THIS SUPPLEMENT USED FOR:

The ingredients in these gummies work synergistically to support:

- Calmness: This supplement supports a state of calmness through its natural ingredients.
- Anxiety Reduction: Chamomile Extract helps reduce anxiety, fostering a sense of tranquillity.
- Promotion of Relaxation: L-Theanine encourages relaxation without drowsiness, aiding in maintaining composure and focus.

Stress Management Skills: Supports the development of stress management skills and emotional equilibrium.

Please note that individual responses to supplements can vary.

BEFORE YOU TAKE THIS SUPPLEMENT:

Do not administer if your child is allergic to any of the ingredients. Take special care when giving children any supplement:

- Do not exceed the daily recommended amount.
- Seek professional advice if they suffer from any **allergies**.
- Seek professional advice if **any other medications** are being taken **or another medical condition** is present.
- If they are taking other supplements, read the label, as these supplements may contain the same ingredients.
- These gummies contain sugar **and are therefore not recommended for diabetics.**

TAKING/USING OTHER MEDICATION:

There are no known interactions at the recommended dosage for healthy individuals. See "PACKAGE INSERT Interactions."

HOW TO TAKE:

The recommended usage is:

Children ages 3-12: Take 2 gummies daily as needed.

IF YOU TAKE MORE THAN YOU SHOULD:

In the event of an overdose, consult your doctor or pharmacist immediately. If neither is available, contact that nearest hospital or medical centre. Treatment is symptomatic and supportive.

POSSIBLE SIDE EFFECTS:

These supplements are generally well-tolerated when taken as directed. Symptoms of overdose may include:

- nausea, vomiting, excessive drowsiness, and gastrointestinal discomfort.

IDENTIFICATION:

Purple, dome shaped gummy with a grape flavour.

PRESENTATION:

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VRYWARING: Hierdie medisyne is nie deur SAPHRA geëvalueer nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of voorkom nie.

Lees alle inligting in die inligtingsblad noukeurig, dit bevat belangrike inligting vir die verbruiker. Die medisyne is beskikbaar sonder 'n dokters voorskrif, vir gebruik as 'n vitamien aanvulling. Nieteenstaande, dit is belangrik dat die produk korrek gebruik moet word om die beste resultate te verkry.

- Moenie die pamflet weggooi nie, dit mag dalk nodig wees om dit weer te lees
- Vra jou apteker indien jy meer inligting of advies nodig het
- Besoek die dokter indien daar kommerwekkende simptome is.

SKEDULERINGSTATUS: Ongeskeduleerd

SAMESTELLING: Elke 2 gummies bevat:

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WAARVOOR WORD HIERDIE AANVULLING GEBRUIK:

Die bestanddele in hierdie gummies werk sinergies om teondersteun:

- Kalmte: Hierdie aanvulling ondersteun 'n toestand van kalmte deur sy natuurlike bestanddele.
- Angsvermindering: Kamille-uittreksel help om angstigheid te verminder, wat 'n gevoel van gemoedsrus bevorder.
- Befondsing van Ontspanning: L-Theanine bevorder ontspanning sonder om verset te maak, en help om selfbeheer en fokus te behou.
- Vaardighede vir die bestuur van stres: Ondersteun die ontwikkeling van vaardighede vir die bestuur van stres en emosionele ewewig.

Let daarop dat individuele reaksies op aanvullings kan verskil.

VOORDAT JY HIERDIE AANVULLING NEEM:

Moenie toedien as jou kind allergies is vir enige van die bestanddele nie.

Wees besonders versigtig wanneer jy enige aanvulling aan kinders gee:

- Moet nie die daaglikse aanbevole hoeveelheid oorskry nie.
- Raadpleeg 'n professionele persoon as hulle aan enige **allergies** ly.

- Raadpleeg 'n professionele persoon as **ander medikasie** geneem word of as daar 'n ander **mediese toestand** teenwoordig is.
- As hulle ander aanvullings neem, lees die etiket, aangesien hierdie aanvullings dieselfde bestanddele kan bevat.
- Hierdie gummies bevat suiker en word dus **nie aanbeveel vir diabele nie**.

INTERAKSIES MET ANDER MEDISYNE:

Daar is geen bekende interaksies by die aanbevole dosis vir gesonde individue nie. Verwys na die «VOUBILJET interaksies»

HOE OM DIT TE GEBRUIK:

Die aanbevole gebruik is:

Ouderdom 3-12: Neem daagliks 2 geteltes soos nodig.

AS JY MEER NEEM AS WAT JY MOET:

In geval van 'n oordosis, raadpleeg onmiddellik jou dokter of apteker. As hulle nie beskikbaar is nie, kontak die naaste hospitaal of mediese sentrum. Behandeling is simptome en ondersteunend.

MOONTLIKE NEWE-EFFEKTE:

Hierdie aanvullings word gewoonlik goed verdra as dit soos voorgeskryf geneem word. Simptome van 'n oordosis kan insluit:

- nausea, braking, oormatige sluimerigheid, en gastro-intestinale ongemak.

IDENTIFIKASIE:

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Julie 2023