

PROPRIETARY NAME AND DOSAGE FORM:

**SLEEP
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	-
GABA (as Gamma Aminobutyric Acid)	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.

INTERACTIONS:

No known interactions with existing conditions at recommended dose.

Medicines that might interact with these gummies are:

- Sedative Medications: Valerian extract and GABA may enhance the sedative effects of these medications, leading to excessive drowsiness and dizziness.
- Benzodiazepines: Valerian extract and GABA 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, ideally 30-90 minutes before bedtime.

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:

- Epilepsy - GABA supplementation may exacerbate or trigger seizures in epileptic patients

- Depression: Valerian extract and GABA may worsen symptoms of depression.
- Liver Disorders: Valerian extract should be used cautiously in individuals with liver conditions.
- Pregnancy and Breastfeeding: Safety of valerian, GABA, and ashwagandha has not been established during pregnancy or breastfeeding.

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:

- dizziness, excessive drowsiness, and gastrointestinal discomfort.

IDENTIFICATION:

Purple, dome shaped gummy with a blackcurrant 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:

**SLEEP
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.

SKEDULERINGSSTATUS: 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	-
GABA (as Gamma Amino-butielariensuur)	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 dieetinnam van die genoemde aktiewe bestanddele voorkom.

KONTRA-LNDIKASIES:

- Hipersensitiwiteit vir enige van die bestanddele.

WAASKUWINGS EN SPESIALE VOORSORGMAATREËLS:

- Groot dosisse mag lei tot maag ongemak.

INTERAKSIES:

Geen bekende interaksies teen die aanbevole dosis.

Medisyne wat kan interaksie hê met die gummies is:

- Sedatiewe Medikasie: Valeriaanekstrak en GABA kan die sederende effekte van hierdie medikasie versterk, wat tot buitensporige downernigheid en duiseligheid kan lei.
- Benzodiazepiene: Valeriaanekstrak en GABA 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, ideaal 30-90 minute voor slaaptid.

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:

- Epilepsie - GABA-supplementasie mag epileptiese pasiënte se aanvalle vererger of uitlok.

- Depressie: Valeriaanekstrak en GABA mag simptome van depressie vererger.
- Lewerstoornisse: Valeriaanekstrak moet versigtig gebruik word in individue met lewerkondisies.
- Swangerskap en Borsvoeding: Die veiligheid van valeriaan, GABA en ashwagandha tydens swangerskap of borsvoeding is nie vasgestel nie.

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 simptomaties en ondersteunend.

Simptome van 'n oordosis kan insluit:

- duiseligheid, buitensporige slaaprigtheid, en gastro-intestinale ongemak

IDENTIFIKASIE:

Pers, koepelvormige gummy met n swartbessie 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.

BERGINGSAAANWYSINGS:

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

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DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING

PAMFLET:

Julie 2023

PROPRIETARY NAME AND DOSAGE FORM:

**SLEEP
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	-
GABA (as Gamma Aminobutyric Acid)	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:

- Restful Sleep: Valerian extract supports restful sleep through its calming effects.
- Relaxation to Fall Asleep Faster: GABA (Gamma Aminobutyric Acid) enhances relaxation, helping you fall asleep faster.
- Reduction of Stress and Anxiety: Valerian extract and L-Theanine contribute to stress and anxiety reduction.
- Healthy Sleep Patterns: Valerian extract and GABA help maintain healthy sleep patterns.
- Improving Overall Sleep Quality: Valerian extract and L-Theanine promote relaxation and improve the overall quality of sleep.

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, ideally 30-90 minutes before bedtime.

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:

- dizziness, excessive drowsiness, and gastrointestinal discomfort.

IDENTIFICATION:

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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.

SKEDULERINGSSTATUS: Ongeskeduleerd

SAMESTELLING: Elke 2 gummies bevat:

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Anders 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.**

WAARVOOR WORD HIERDIE AANVULLING GEBRUIK:

Die bestanddele in hierdie jellietjies werk sinergies om teondersteun:

- Rusbenewende Slaap: Valeriaan-uittreksel ondersteun rusbenewende slaap deur sy kalmerende effekte.
 - Ontspanning om Vinniger In Slaap te Val: GABA (Gamma Aminobutiëriese Suur) verbeter ontspanning, wat jou help om vinniger in slaap te val.
 - Vermindering van Stres en Angs: Valeriaan-uittreksel en L-Theanine dra by tot die vermindering van stres en angs.
 - Gesonde Slaappatrone: Valeriaan-uittreksel en GABA help om gesonde slaappatrone te handhaaf.
 - Verbetering van die Algehele Slaapkwaliteit: Valeriaan-uittreksel en L-Theanine bevorder ontspanning en verbeter die algehele kwaliteit van slaap.
- 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 besonder 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 daaglik 2 jellietjies soos nodig, ideaal 30-90 minute voor slaaptyd.

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:

- duiseligheid, buitensporige slaapprogheid, en gastro-intestinale ongemak.

IDENTIFIKASIE:

Pers, koepelvormige gummy met 'n swartbessie geur.

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Julie 2023