

PROPRIETARY NAME AND DOSAGE FORM:

SLEEP SUPPORT TABLETS (30)

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 tablet contains:

Ingredients	Elemental value	*NRV
Valerian Extract 4:1 - Valeriana officinalis L.. (Parts: Root)	300 mg	-
GABA (as Gamma Aminobutyric Acid)	125 mg	-
Ashwagandha Extract 15:1 - Withania somnifera (L.) Dunal (Parts: Root)	100 mg	-
* South African Nutrient reference values for individuals 4 years and older - Not established		

Other Ingredients: Microcrystalline cellulose, magnesium stearate, silicon dioxide & coating.

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 stomach upset, dizziness and headache.

INTERACTIONS:

No known interactions with existing conditions at recommended dose.

Medicines that will interact with Sleep Support are:

- Sedative Medications: Valerian extract and GABA may enhance the sedative effects of these medications, leading to excessive drowsiness and dizziness.
- Antidepressants: Combining with ashwagandha may increase the risk of 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:

- Adults take 1 tablet daily 30-90 minutes before intended sleep.

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:

- Hypertension - Ashwagandha may lower blood pressure in patients taking medication for hypertension
- 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 oblong pressed tablet.

PRESENTATION:

Packaged as a printed box with tamperproof seal, labelled with clear, detailed information printed on the box. Contents are 3 blister packs of 10 oblong tablets each, containing 30 tablets in total.

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

vitatech® NAPPI CODE:

3001493001

Claim it from your medical aid.

HANDELSNAAM EN DOSERINGSVORM:

SLEEP SUPPORT TABLETTE (30)

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 diagnose, behandeling, genesing of voorkoming van enige siekte nie.

SKEDULERINGSSTATUS: Ongeskeduleerd

SAMESTELLING: Elke tablet bevat:

Ingredients	Elemental value	*NRV
Valeriaan Ekstrak 4:1 - Valeriana officinalis L.. (Dele: Wortel)	300 mg	-
GABA (as Gamma Amino-butielariensuur)	125 mg	-
Ashwagandha Extract 15:1 - Withania somnifera (L.) Dunal (Dele: Wortel)	100 mg	-
* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer - Nie vasgestel nie		

Ander bestanddele is: Mikrokristallyn sellulose, magnesiumstearaat, silikoondioksied & omhulsel

FARMAKOLOGIESE KLASSEKASIE:

34.13 Kategorie D (Gesondheidsaanvuller) [S0]

FARMAKOLOGIESE WERKING: Gesondheidsaanvuller

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

KONTRA-INDIKASIES:

- Hipersensitiwiteit vir enige van die bestanddele.

WAASKUWINGS EN SPESIALE VOORSORGMATREËLS:

- Groot dosisse mag lei tot maagklampte, duiseligheid en hoofpyn.

INTERAKSIES:

Geen bekende interaksies teen die aanbevole dosis.

Medisyne wat sal interageer met Slaapondersteuning is:

- Sedatiewe Medikasie: Valeriaanekstrak en GABA kan die sederende effekte van hierdie medikasie versterk, wat tot buitensporige downernigheid en duiseligheid kan lei.
- Antidepressante: Kombinasie met ashwagandha kan die risiko van downernigheid en duiseligheid verhoog.
- Benzodiazepiene: Valeriaanekstrak en GABA kan die effekte van hierdie medikasie versterk, wat tot verhoogde sedasie kan lei.

DOSIS EN GEBRUIKSAANWYSINGS:

Die aanbevole gebruik is:

- Volwassenes neem 1 tablet daaglik 30-90 minute voor die beoogde slaap.

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:

- Hoë Bloeddruk - Ashwagandha mag die bloeddruk van pasiënte wat medikasie vir hipertensie gebruik, verlaag.
- Epilepsie - GABA-supplementasie mag epileptiese pasiënte se aanvalle vererger of uitlok.
- Depressie: Valeriaanekstrak en GABA mag simptome van depressie vererger.
- Lewerstornisse: 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 langwerpige gedrukte tablet.

AANBIEDING:

Verpak as 'n gedrukte boks met 'n verseëde sertifikaat, gemerk met duidelike, gedetailleerde inligting wat op die boks gedruk is. Die inhoud bestaan uit 3 blaaspakke met elk 10 langwerpige tablette, wat 'n totaal van 30 tablette bevat.

BERGINGSAAANWYSINGS:

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

REGISTRASIE NOMMER:

Word ge-allockeer.

NAAM EN BESIGHEIDS ADRES VAN DIE APPLIKANT:

Vitatech

Adress: Cnr Parkin & Delson Street

North End, Gqeberha, 6001, Suid Afrika.

Tel: 041 816 3100

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Webwerf: www.vitatechhealth.com

DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET:

Julie 2023

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SLEEP SUPPORT TABLETS (30)

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

CONTAINS: Each tablet contains:

Ingredients	Elemental value	*NRV
Valerian Extract 4:1 - Valeriana officinalis L.. (Parts: Root)	300 mg	-
GABA (as Gamma Aminobutyric Acid)	125 mg	-
Ashwagandha Extract 15:1 - Withania somnifera (L.) Dunal (Parts: Root)	100 mg	-
* South African Nutrient reference values for individuals 4 years and older - Not established		

Other Ingredients: Microcrystalline cellulose, magnesium stearate, silicon dioxide & coating.

WHAT IS THIS SUPPLEMENT USED FOR:

- Restful sleep - Through relaxing effects of valerian and anxiolytic properties of ashwagandha
- Relaxation to fall asleep faster - By enhancing GABA levels which promote sleep
- Reduction of stress and anxiety - Ashwagandha has adaptogenic properties to help manage stress
- Healthy sleep patterns - Maintaining consistent sleep-wake cycles with valerian and ashwagandha
- Improving overall sleep quality - By promoting relaxation and deeper, more restorative stages of sleep.

BEFORE YOU TAKE THIS SUPPLEMENT:

Do not take if you are allergic to any of the ingredients.

Take special care when taking any supplement:

- Do not exceed the daily recommended amount.
- Seek professional advice if suffering from any **allergies**.
- Seek professional advice if **any other medications** are being taken or another medical condition is present.
- If you are taking other supplements, read the label as these supplements may contain the same ingredients.
- If you are **pregnant or breast feeding using this supplement is not advised** – consult with your healthcare provider.
- As this is a sleep supplement, do not use if you need to **drive or operate heavy machinery** as it may make you drowsy or impair your ability to do so safely.

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:

- Adults take 1 tablet daily 30-90 minutes before intended sleep.

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.

If you experience any unusual or severe side effects, discontinue use, and seek medical attention.

IDENTIFICATION:

Purple oblong pressed tablet.

PRESENTATION:

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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 tablet bevat:

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Anders bestanddele is: Mikrokristallyn sellulose, magnesiumstearaat, silikoondioksied & omhulsel

WAARVOOR WORD HIERDIE AANVULLING GEBRUIK:

- Rusgevend slaap - Deur die ontspannende effekte van valerian en anxiolitiese eienskappe van ashwagandha
- Ontspanning om vinniger in te slaap - Deur GABA-vlakke te verhoog wat slaap bevorder
- Vermindering van stres en angs - Ashwagandha het aanpassingsvermoë om stres te bestuur
- Gesonde slaappatrone - Deur konstante slaap-waak siklusse met valerian en ashwagandha te handhaaf
- Algehele slaapkwaliteit verbeter - Deur ontspanning en dieper, meer herstellende fases van slaap te bevorder.

VOORDAT JY HIERDIE AANVULLING NEEM:

Moenie dit inneem as jy allergies is vir enige van die bestanddele nie.

Wees versigtig wanneer jy enige aanvulling gebruik:

- Moet nie die daaglikse aanbevole hoeveelheid oorskry nie.
- Raadpleeg 'n professionele persoon as jy aan enige **allergieë** ly.
- Raadpleeg 'n professionele persoon as enige **ander medikasie** gebruik word of 'n ander mediese toestand teenwoordig is.
- As jy ander aanvullings gebruik, lees die etiket aangesien hierdie aanvullings dieselfde bestanddele kan bevat.
- As jy **swanger is of borsvoeding gee, word die gebruik van hierdie aanvulling nie aanbeveel nie** - raadpleeg jou gesondheidsorgverskaffer.

- Aangesien dit 'n slaapaanvulling is, moet dit nie gebruik word as jy moet bestuur of swaar masjinerie moet bedryf nie, aangesien dit jou slaperig kan maak of jou vermoë om dit veilig te doen, kan benadeel.

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:

- Volwassenes neem 1 tablet daaglik 30-90 minute voor die beoogde slaap.

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 slaaprigtheid, en gastro-intestinale ongemak

IDENTIFIKASIE:

Pers langwerpige gedrukte tablet.

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