

PROFESSIONAL INFORMATION
D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE

BIOGEN RE | NU BEAUTY SLEEP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:		% NRV*
<i>Valeriana officinalis</i> L. (Valerian) [Root; 4:1 Extract providing 300 mg of dried herb equivalent]	75,00 mg	
<i>Passiflora incarnata</i> L. (Passionflower) [Herb; 4:1 Extract providing 100 mg dried herb equivalent]	25,00 mg	
<i>Melissa officinalis</i> L. (Lemon balm) [Leaf; 10:1 Extract providing 200 mg dried herb equivalent]	20,00 mg	
Pyridoxine (Vitamin B ₆) [from Pyridoxine hydrochloride]	10,00 mg	588 %

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)

Sugar free

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Size 0 red bovine gelatin capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN RE | NU BEAUTY SLEEP, supports healthy sleep and rejuvenation.

4.2 Posology and method of administration

Adults: Take one capsule daily 30 – 60 minutes before bed time, as needed, or as recommended by your healthcare provider. Extended use is not recommended.

The safety and efficacy of BIOGEN RE | NU BEAUTY SLEEP in children has not yet been established. Not allowed in children under 18 years.

4.3 Contraindications

- If you have a hypersensitivity to Valerian, Passionflower, Lemon balm, Vitamin B₆ or any of the excipients listed in 6.1.
- Not recommended during pregnancy and lactation.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN RE | NU BEAUTY SLEEP.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- BIOGEN RE | NU BEAUTY SLEEP can cause drowsiness in some patients.
- Consult a healthcare provider if sleeplessness persists continuously for more than 4 weeks (chronic insomnia) or worsen.
- When used chronically and abruptly stopped, symptoms of withdrawal such as tachycardia, anxiety, irritability, and insomnia might occur. Patients are advised to taper doses slowly after extended use.
- BIOGEN RE | NU BEAUTY SLEEP is not recommended for use in children under the age of 18 years.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction
Interactions with Medicines

- The concomitant use of medication with similar or opposing effects, such as Benzodiazepines, Barbiturates or Central nervous system (CNS) depressants, St. John's wort is not recommended as it may have additive therapeutic and adverse effects.
- The concomitant use of BIOGEN RE | NU BEAUTY SLEEP and certain medications, such as Antiepileptic and Antihypertensive medicine, Aminodaron, Cycloserine, Phenobarbital, Phenytoin and Theophylline may affect vitamin B₆ levels and have additive effects or may reduce therapeutic effects of medicine.
- Valerian can have additive sedative effects when used with Alprazolam. Also, valerian in high doses might modestly increase Alprazolam levels, though this is not likely to be clinically significant.
- Concomitant use of Organic Anion-transporting polypeptides and BIOGEN RE | NU BEAUTY SLEEP might reduce the bioavailability of OATP2B1 and OATP1A2 substrates.
- Concomitant use of BIOGEN RE | NU BEAUTY SLEEP with Antihistamines, and Antispasmodics may cause interactions.

Interactions with Diseases / Impairments

- As BIOGEN RE | NU BEAUTY SLEEP has sedative effects which might cause additive CNS depression when combined with anesthesia and other medications used preoperatively. Patients are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).

Interactions with Foods

- Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.
- Do not take with alcohol as it may increase the risk of sedation.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. Not recommended for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

BIOGEN RE | NU BEAUTY SLEEP may cause drowsiness, sedation, dizziness, psychomotor slowing and insomnia, it is advised that patients taking BIOGEN RE | NU BEAUTY SLEEP should not drive or operate machinery until they are reasonably certain that it does not adversely affect their ability to drive or operate machinery.

4.8 Undesirable effects

Orally, Valerian, Passionflower and Lemon balm is generally is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:

Frequent: Dry mouth, diarrhoea, vomiting, decreased appetite, nausea and abdominal pain or discomfort.

Nervous system disorders:

Frequent: Anxiety, confusion, dizziness, irritability and insomnia might occur. Somnolence, sedation, psychomotor slowing, lethargy, headaches and fatigue.

Cardiovascular:

Frequency unknown: Cardiac failure, and chest tightness.

Description of selected adverse reactions

BIOGEN RE | NU BEAUTY SLEEP may cause several adverse reactions, of which dizziness, drowsiness, and mental slowness. Other side effects include headache, gastrointestinal upset, excitability, and vivid dreams. When used chronically and abruptly stopped, symptoms of withdrawal such as tachycardia, anxiety, irritability, and insomnia might occur. Advise patients to taper doses slowly after extended use.

Paediatric Population

BIOGEN RE | NU BEAUTY SLEEP is not recommended for use in children under the age of 18 years.

Other special populations

No clinical data are available on the effects of BIOGEN RE | NU BEAUTY SLEEP on other special populations.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine 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: <http://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Side effects listed in section 4.8 can be precipitated and/ or be of increased severity. In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

BIOGEN RE | NU BEAUTY SLEEP, supports healthy sleep and rejuvenation.

Pharmacodynamic properties

Mechanism of action:

Valeriana officinalis L. (Valerian) constituents may inhibit the enzyme system responsible for the central catabolism of gamma-aminobutyric acid (GABA), increasing GABA concentrations and decreasing CNS activity. Valerian may also bind directly to GABA-A receptors and stimulate the release and reuptake of GABA. Valerian might affect sleep regulation via activity on adenosine and serotonin (5-HT₁) receptors.

Passiflora incarnata L. (Passionflower) contains many alkaloids, flavonoids as well as many organic compounds such as organic acids. Modulation and mediation of the GABAergic system, including affinity to the *GABA_A* and *GABA_B* receptors and GABA uptake.

Melissa officinalis L. (Lemon balm) is known to be a potent *in vitro* inhibitor of rat brain GABA transaminase and monoamine oxidase A (MAO-A).

Vitamin B₆ in its biologically active coenzyme form pyridoxal 5'-phosphate, is involved in a wide range of biochemical reactions, including the metabolism of amino acids and glycogen, the synthesis of nucleic acids, hemoglobin, sphingomyelin and other sphingolipids, and the synthesis of the neurotransmitters serotonin, dopamine, norepinephrine and gamma-aminobutyric acid.

Pharmacodynamic effects:

Valeriana officinalis L. (Valerian) depresses the CNS at the limbic and subcortical levels of the brain. It produces an anti-anxiety effect by influencing the effect of the neurotransmitter gamma-aminobutyric acid on its receptor in the ascending reticular activating system, which increases inhibition and blocks both cortical and limbic arousal after stimulation of the reticular formation.

Passiflora incarnata L. (Passionflower) extract is considered a benzodiazepine receptor partial agonist.

Melissa officinalis L. (Lemon balm) has sedative, spasmolytic, and antibacterial effects. Lemon balm contains the flavonoids, monoterpenoid and sesquiterpenes.

Vitamin B₆ is a water-soluble vitamin used in the prophylaxis and treatment of vitamin B₆ deficiency and peripheral neuropathy in those receiving isoniazid (isonicotinic acid hydrazide, INH).

Pharmacokinetic properties

Absorption:

Passiflora incarnata L. (Passionflower) when administered orally, drug is well absorbed through the GI tract. Absorption usually occurs within 30 min to 90 min post oral ingestion.

Valeriana officinalis L. (Valerian) absorption usually occur within 1-2 hours.

Melissa officinalis L. (Lemon balm) peak concentration of rosmarinic acid at 30 min to 1 hour post ingestion, before returning to baseline levels.

Vitamin B₆ are readily absorbed from the gastrointestinal tract, except in malabsorption syndromes. Pyridoxine is absorbed mainly in the jejunum. The C_{max} of pyridoxine is achieved within 5.5 hours.

No clinical data are available on the effects of BIOGEN RE | NU BEAUTY SLEEP.

Distribution:

Passiflora incarnata L. (Passionflower) distributed widely throughout the body, and is found to be about 85 % protein-bound.

Valeriana officinalis L. (Valerian), valepotriates were found in the stomach lining and in the intestines.

Melissa officinalis L. (Lemon balm) are rapidly absorbed through the lungs and cross the blood-brain barrier.

Vitamin B₆ is released into the circulation (accounting for at least 60 % of circulating vitamin B₆) and is highly protein bound, primarily to albumin.

Metabolism:

Passiflora incarnata L. (Passionflower) metabolized in the liver to inactive metabolites.

Valeriana officinalis L. (Valerian), metabolic decomposition has been found in the blood, liver, kidneys, heart, lungs, and brain.

Melissa officinalis L. (Lemon balm) are metabolized by gut microbiota. As rosmarinic acid (RA) is also metabolized to methyl-RA, caffeic acid and ferulic acid. RA and its metabolites are present in plasma and urine, predominantly as conjugated forms such as glucuronide or sulfate. Metabolism of RA may be altered by the presence of other factors such as dietary phenolics, food intake, disease states and drugs.

Vitamin B₆ is primarily metabolized in the liver.

Excretion:

Passiflora incarnata L. (Passionflower) metabolites are excreted in urine as glucuronide conjugates.

Valeriana officinalis L. (Valerian) glucuronidation renders the compounds more hydrophilic, facilitating their excretion in bile or urine

Melissa officinalis L. (Lemon balm) are found to be rapidly metabolised and excreted, approximately 50% of the oral dose excreted within 24 hours. Eliminated through urine but most of the compound was excreted in feces, suggesting a role for the first-pass metabolism through the skin.

Vitamin B₆, the metabolite, 4-pyridoxic acid, is inactive and is excreted in urine.

Preclinical safety data

When used orally and appropriately, short-term in adults, Valerian, Passionflower and Lemon balm is recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Magnesium stearate
Microcrystalline cellulose

6.2 Incompatibilities

No compatibility studies has been performed, BIOGEN RE | NU BEAUTY SLEEP must not be mixed with other medications.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store in a cool, dry place at or below 25 °C. Do not use after expiry date
Keep the container tightly closed.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

175 ml PET container with a Biogen lid. Packed in a unit carton.
BIOGEN RE | NU BEAUTY SLEEP is a size 0 Red Bovine gelatin capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 011 589 2322

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

November 2021.

JOB: B RE NU_Beauty Sleep_30s		SIZE: 210mm x 345mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
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<input type="checkbox"/> Spot UV	<input type="checkbox"/> Doming	<input type="checkbox"/> Embossing	
PLEASE CHECK CAREFULLY			
Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: [S0]

BIOGEN RE | NU BEAUTY SLEEP

Valerian | Passionflower | Lemon balm | Vitamin B₆.
Sugar Free.

**D 34.12 Multiple Substance Formulation.
Complementary Medicine: Health Supplement**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.
BIOGEN RE | NU BEAUTY SLEEP is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN RE | NU BEAUTY SLEEP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN RE | NU BEAUTY SLEEP with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What BIOGEN RE | NU BEAUTY SLEEP is and what it is used for.
2. What you need to know before you take BIOGEN RE | NU BEAUTY SLEEP.
3. How to take BIOGEN RE | NU BEAUTY SLEEP.
4. Possible side effects.
5. How to store BIOGEN RE | NU BEAUTY SLEEP.
6. Contents of the pack and other information.

1. WHAT BIOGEN RE | NU BEAUTY SLEEP IS AND WHAT IT IS USED FOR
BIOGEN RE | NU BEAUTY SLEEP, supports healthy sleep and rejuvenation.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BIOGEN RE | NU BEAUTY SLEEP

Do not take BIOGEN RE | NU BEAUTY SLEEP:

- If you have a hypersensitivity to Valerian, Passionflower, Lemon balm, Vitamin B₆ or any of the other ingredients listed (see section 6).
- Not recommended during pregnancy and lactation.

Warnings and precautions

Special care should be taken with BIOGEN RE | NU BEAUTY SLEEP.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- BIOGEN RE | NU BEAUTY SLEEP can cause drowsiness in some patients.
- Consult a healthcare provider if sleeplessness persists continuously for more than 4 weeks (chronic insomnia) or worsen.
- When used chronically and abruptly stopped, symptoms of withdrawal such as tachycardia, anxiety, irritability, and insomnia might occur. Patients are advised to taper doses slowly after extended use.
- BIOGEN RE | NU BEAUTY SLEEP is not recommended for use in children under the age of 18 years.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

Children and adolescents

BIOGEN RE | NU BEAUTY SLEEP is not recommended for use in children under the age of 18 years.

Other medicines and BIOGEN RE | NU BEAUTY SLEEP

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine.

It is advised to consult your doctor if you want to take BIOGEN RE | NU BEAUTY SLEEP combined with other medicines or treatments such as:

- Benzodiazepines, Barbiturates or Central nervous system (CNS) depressants and St. John's wort as it may have additive therapeutic and adverse effects.
- Antiepileptic and Antihypertensive medicine, Amiodarone, Cycloserine, Phenobarbital, Phenytoin and Theophylline as it may affect Vitamin B₆ levels and have additive effects or may reduce therapeutic effects of the medicine.
- Alprazolam, as Valerian can have additive sedative effects when used with alprazolam.
- Organic Anion-transporting polypeptides as it might reduce the bioavailability of OATP2B1 and OATP1A2 substrates.
- Antihistamines and Antispasmodics as it may cause interactions.

BIOGEN RE | NU BEAUTY SLEEP with food and drink

- Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.
- Consuming alcohol in combination with BIOGEN RE | NU BEAUTY SLEEP may increase the risk of sedation and drowsiness.

Pregnancy, breastfeeding and fertility

Not recommended for use during pregnancy or lactation.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machinery

No studies on the effects on the ability to drive or use machinery have been performed. It is possible that BIOGEN RE | NU BEAUTY SLEEP would affect the ability to drive or operate machinery, as BIOGEN RE | NU BEAUTY SLEEP may cause delayed reactions, drowsiness and sedation. Please exercise caution until you are certain that your ability to perform such activities is not affected.

3. HOW TO TAKE BIOGEN RE | NU BEAUTY SLEEP

Do not share your medicines with any other person.

Always take BIOGEN RE | NU BEAUTY SLEEP exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: Take one capsule daily 30 – 60 minutes before bed time, as needed, or as recommended by your healthcare provider. Extended use is not recommended.

The safety and efficacy of BIOGEN RE | NU BEAUTY SLEEP in children has not yet been established. Not allowed in children under 18 years.

If you take more BIOGEN RE | NU BEAUTY SLEEP than you should

No known information. In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN RE | NU BEAUTY SLEEP oil with you so the doctor will know what you have taken.

If you forget to take BIOGEN RE | NU BEAUTY SLEEP

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

BIOGEN RE | NU BEAUTY SLEEP can have side effects.

Not all side effects reported for BIOGEN RE | NU BEAUTY SLEEP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN RE | NU BEAUTY SLEEP, please consult your healthcare provider for advice.

Side effects associated with BIOGEN RE | NU BEAUTY SLEEP:

Frequent:

- Diarrhea, dry mouth, vomiting, decreased appetite, nausea and abdominal pain or discomfort.
- Anxiety, confusion, dizziness, irritability and insomnia might occur. Somnolence, sedation, delayed reactions, lethargy, dizziness and fatigue.

Frequency unknown:

- Cardiac failure and chest tightness.

Should your general health worsen or if you experience any untoward effects while BIOGEN RE | NU BEAUTY SLEEP, please consult your doctor, pharmacist or other healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reactions Reporting Form**, found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BIOGEN RE | NU BEAUTY SLEEP.

5. HOW TO STORE BIOGEN RE | NU BEAUTY SLEEP

- Store at or below 25 °C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BIOGEN RE | NU BEAUTY SLEEP contains

Active ingredients per capsule is *Valeriana officinalis* L. (Valerian) 75,00 mg, *Passiflora incarnata* L. (Passionflower) 25,00 mg, *Melissa officinalis* L. (Lemon balm) 20,00 mg, Pyridoxine (Vitamin B₆) 10,00 mg.

The other ingredients are magnesium stearate and microcrystalline cellulose.

What BIOGEN RE | NU BEAUTY SLEEP looks like and contents of the pack

175 ml PET container with a Biogen lid. Packed in a unit carton.

BIOGEN RE | NU BEAUTY SLEEP is a size 0 Red Bovine gelatin capsules.

HOLDER OF CERTIFICATE OF REGISTRATION

Biogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 011 589 2322

THIS LEAFLET WAS LAST REVISED IN

November 2021

REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS: [S0]

BIOGEN RE | NU BEAUTY SLEEP

Valeriaan | Grenadella | Suurlemoenbalsem | Vitamien B₆.
Suikervry.

**D 34.12 Veelvoudige Bestanddeel Formulasie.
Komplementêre Medisyne. Gesondheidsaanvulling.**

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir u.
BIOGEN RE | NU BEAUTY SLEEP is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN RE | NU BEAUTY SLEEP nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN RE | NU BEAUTY SLEEP met enigiemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of apteaker indien u verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is BIOGEN RE | NU BEAUTY SLEEP en waarvoor word dit gebruik.
2. Wat u moet weet voordat u BIOGEN RE | NU BEAUTY SLEEP neem.
3. Hoe om BIOGEN RE | NU BEAUTY SLEEP te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BIOGEN RE | NU BEAUTY SLEEP te bêre.
6. Inhoud van die verpakking en ander inligting.

1. WAT IS BIOGEN RE | NU BEAUTY SLEEP EN WAARVOOR WORD DIT GEBRUIK

BIOGEN RE | NU BEAUTY SLEEP, ondersteun gesonde slaap en verjonging.

2. WAT JY MOET WEET VOORDAT JY BIOGEN RE | NU BEAUTY SLEEP

Moenie BIOGEN RE | NU BEAUTY SLEEP neem nie:

- Indien u allergies is vir Valeriaan, Grenadella, Suurlemoenbalsem, Vitamien B₆ of enige van die ander bestanddele gelys (sien afdeling 6).
- Nie aanbeveel tydens swangerskap en laktasie nie.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet toegepas word met die gebruik van BIOGEN RE | NU BEAUTY SLEEP.

Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik. Let asseblief op die volgende:

- BIOGEN RE | NU BEAUTY SLEEP kan in by sommige pasiënte slaperigheid veroorsaak.
- Raadpleeg u gesondheidspraktisyn as slapeloosheid vir langer as 4 weke onderbroke aanhou (chroniese slapeloosheid) of vererger.
- As dit chronies gebruik word en skielik gestaak word, kan onttrekkingsimptome soos tagikardie, angs, prikkelbaarheid en slapeloosheid voorkom. Pasiënte word aangeraai om die dosisse stadig te verminder na langdurige gebruik.
- BIOGEN RE | NU BEAUTY SLEEP word nie aanbeveel vir gebruik onder kinders jonger as 18 jaar nie.

Voedingsaanvullings moet nie 'n gebalanseerde dieet vervang nie. Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

Kinders en adolessente

BIOGEN RE | NU BEAUTY SLEEP word nie vir kinders onder die ouderdom van 18 jaar aanbeveel nie.

Ander medisyne en BIOGEN RE | NU BEAUTY SLEEP

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN RE | NU BEAUTY SLEEP wil kombineer saam met ander medisyne of behandelinge soos:

- Bensodiasiepiene, Barbiturate of Sentrale senuweestelsel (SSW) depressante, en Johanneskruid, omrede dit adisionele terapeutiese en nadelige gevolge kan hê.
- Antiepileptiese en Antihypertensiewe medisyne, Amlodaron, Sikloserien, Fenobarbital, Fenoitoien en Teofillie, omrede dit kan Vitamien B₆-vlakke kan beïnvloed en 'n adisionele effek kan hê of die terapeutiese effek van medisyne kan verminder.
- Alprazolam, omrede Valeriaan adisionele kalmerende effekte kan hê.
- Organiese Anioon-vervoerende polipeptiede en omrede dit die biobeskikbaarheid van OATP2B1 - en OATP1A2-substrate kan verminder.
- Antihistamiene en Antispasmodika omrede dit interaksies kan veroorsaak.

BIOGEN RE | NU BEAUTY SLEEP met kos en drinkgoed

- Gebruik hierdie produk saam met voedsel as deel van 'n gesonde, gebalanseerde dieet, nie as 'n plaasvervanger daarvoor nie.
- Die gebruik van alkohol in kombinasie met BIOGEN RE | NU BEAUTY SLEEP kan die risiko van sedasie en lomerigheid verhoog.

Swangerskap, borsvoeding en vrugbaarheid.

Nie aanbeveel vir gebruik tydens swangerskap en laktasie nie.

Indien u swanger is of u baba borsvoed, dink dat u swanger is, of van plan is om 'n baba te hê, raadpleeg u dokter, apteaker of gesondheidsorgwerker voordat u hierdie medisyne gebruik.

Bestuur en die gebruik van masjiene

Geen studies is uitgevoer oor die uitwerking op die vermoë om te bestuur of masjinerie te gebruik nie. Dit is moontlik dat BIOGEN RE | NU BEAUTY SLEEP die vermoë om te bestuur of gebruik van masjinerie kan beïnvloed, aangesien BIOGEN RE | NU BEAUTY SLEEP vertraagde reaksies, lomerigheid en sedasie kan veroorsaak. Wees asseblief versigtig totdat u seker is dat u vermoë om sulke aktiwiteite uit te voer nie beïnvloed word nie.

3. HOE OM BIOGEN RE | NU BEAUTY SLEEP TE NEEM

Moenie u medisyne met enigiemand anders deel nie.

Neem, BIOGEN RE | NU BEAUTY SLEEP altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat u dokter of apteaker vir u aanbeveel het. Vra gerus u dokter of apteaker indien u onseker is.

Volwassenes: Neem een kapsule daaglik 30 - 60 minute voor slaaptyd, soos nodig, of soos aanbeveel deur u gesondheidsorgpraktisyn. Langtermyn gebruik word nie aanbeveel nie.

Die veiligheid en doeltreffendheid van BIOGEN RE | NU BEAUTY SLEEP in kinders is nog nie vasgestel nie. Word nie toegelaat in kinders onder 18 jaar nie.

Wat om te doen indien jy meer BIOGEN RE | NU BEAUTY SLEEP geneem het as wat u moet

Geen bekende informasie. Indien u meer BIOGEN RE | NU BEAUTY SLEEP geneem het as wat u moes, of in die geval van 'n oordosis, raadpleeg u dokter of apteaker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende BIOGEN RE | NU BEAUTY SLEEP olie saam sodat die dokter kan sien wat u ingeneem het.

Indien u vergeet om BIOGEN RE | NU BEAUTY SLEEP te neem

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. MOONTLIKE NUWE-EFFEKTE

BIOGEN RE | NU BEAUTY SLEEP kan nuwe-effekte hê.

Nie alle nuwe-effekte wat aangemeld is vir BIOGEN RE | NU BEAUTY SLEEP is in hierdie voublaaij ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN RE | NU BEAUTY SLEEP, raadpleeg u gesondheidsorgwerker vir advies.

Nuwe-effekte geassosieer met BIOGEN RE|NU BEAUTY SLEEP:

Algemeen:

- Diarree, droë mond, braking, verminderde eetlus, naarheid en of ongemak.
- Angs, verwarring, duiseligheid, prikkelbaarheid en slapeloosheid kan voorkom. Slaperigheid, sedasie, vertraagde reaksies, lusteloosheid, duiseligheid en moegheid.

Frekwensie onbekend:

- Hartversaking en toegetrokte bors.

Raadpleeg u dokter, apteaker of ander geneesheer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl u BIOGEN RE | NU BEAUTY SLEEP neem.

As u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet u dokter of apteaker daarvan in kennis gestel word.

Rapportering van nuwe-effekte

Indien u nuwe-effekte ondervind, bespreek dit met u dokter of apteaker. U kan ook nuwe-effekte aan SAHPRA rapporteer via die **Adverse Drug Reactions Reporting Form**, wat aanlyn by SAHPRA se publikasies beskikbaar is

<http://www.sahpra.org.za/Publications/Index/8>.

Deur nuwe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN RE | NU BEAUTY SLEEP te verskaf.

5. HOE OM BIOGEN RE | NU BEAUTY SLEEP TE BÊRE

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteaker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. INHOUD VAN DIE PAK EN ANDER INLIGTING

Wat BIOGEN RE | NU BEAUTY SLEEP bevat

Aktiewe bestanddele per kapsule, *Valeriaan officinalis* L. (Valeriaan) 75,00 mg, *Passiflora incarnata* L. (Grenadella) 25,00 mg, *Melissa officinalis* L. (Suurlemoenbalsem) 20,00 mg, Piridoksien (Vitamien B₆) 10,00 mg.

Die ander bestanddele is magnesiumstearaat en mikrokristallyne sellulose.

Hoe BIOGEN RE | NU BEAUTY SLEEP lyk en inhoud van die verpakking

175 ml PET-houer met 'n Biogen-deksel. Verpak in 'n karton eenheid.
BIOGEN RE | NU BEAUTY SLEEP is 'n grootte 0 Rooi Bees gelatienkapsules.

HOUER VAN DIE REGISTRASIESERTIFIKAAT

Biogen
Stagweg 23, Glen Austin, Suid Afrika
info@biogen.co.za
www.biogen.co.za
Tel: 011 589 2322

HIERDIE INLIGTINGSBLAD IS HERSIEN IN

November 2021.

REGISTRASIONOMMER

Sal met registrasie deur SAHPRA aangedui word.

JOB: B RE NU_Beauty Sleep_30s	SIZE: 210mm x 345mm
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
COLOURS:	FINISHING:
<input checked="" type="checkbox"/> K <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss
<input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Spot UV <input type="checkbox"/> Dornig <input type="checkbox"/> Embossing
PLEASE CHECK CAREFULLY	
Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	