

PROFESSIONAL INFORMATION
**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 NIGHT BURN**
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegicapsule contains:

<i>Withania somnifera</i> (L.) Dunal (Ashwaganda Root Extract) [Root, 15:1 extract powder]	150,00 mg
InnoSlim® [<i>Panax notoginseng</i> (Burkill) F.H.Chen Root Extract and <i>Astragalus membranaceus</i> (Fisch.) Bunge Root Extract]	125,00 mg
L-Theanine	100,00 mg
L-Tryptophan	50,00 mg
Gamma-aminobutyric acid (GABA)	50,00 mg
BioPerine® (<i>Piper nigrum</i> (Black Pepper Extract) [fruit, 50:1 extract standardized to 95 % piperine])	5,00 mg

Vegetable capsule shell containing hypromellose.

Sugar free

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetable capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN NIGHT BURN is indicated as an aid to a weight management program, including an energy-restricted diet and regular exercise.

4.2 Posology and method of administration

Adults: Take 2 capsules 30 minutes before bed time, or as recommended by your healthcare practitioner. Suitable for consumption after 16h00. BIOGEN NIGHT BURN may also be used twice daily when you are taking a break from BIOGEN RAGE THERMO, for example on weekends.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients (see section 6.1).
- Pregnancy and lactation (see section 4.6).

4.4 Special care should be taken with BIOGEN NIGHT BURN:

High or low blood pressure:

BIOGEN NIGHT BURN might decrease blood pressure. This could cause blood pressure to go too low in people with low blood pressure; or interfere with medications used to treat high blood pressure. BIOGEN NIGHT BURN should be used cautiously if you have low blood pressure or take medications for your blood pressure.

Stomach ulcers:

BIOGEN NIGHT BURN can irritate the gastrointestinal (GI) tract. Do not use BIOGEN NIGHT BURN if you have a stomach ulcer.

"Auto-immune diseases" such as multiple sclerosis (MS), lupus (systemic lupus erythematosus, SLE), rheumatoid arthritis (RA), or other conditions:

BIOGEN NIGHT BURN might cause the immune system to become more active, and this could increase the symptoms of auto-immune diseases. If you have one of these conditions, it is best to avoid using BIOGEN NIGHT BURN.

Thyroid disorders:

BIOGEN NIGHT BURN might increase thyroid hormone levels. BIOGEN NIGHT BURN should be used cautiously or avoided if you have a thyroid condition or take thyroid hormone medications.

Surgery:

BIOGEN NIGHT BURN may slow down the central nervous system. Healthcare providers worry that anesthesia and other medications during and after surgery might increase this effect. Stop taking BIOGEN NIGHT BURN at least 2 weeks before a scheduled surgery.

Diabetes:

BIOGEN NIGHT BURN might affect blood glucose levels, which might interfere with blood glucose control in patients with diabetes mellitus (see section 4.5).

4.5 Interaction with other medicines and other forms of interaction

Sedative medications (CNS depressants): Consumption with other products with sedative effects (e.g. clonazepam, lorazepam, phenobarbital, zolpidem) is not recommended.

Medicines increasing serotonin: Consumption with other medicines which increase serotonin (e.g. Some of these medications include fluoxetine (Prozac), paroxetine (Paxil), sertraline (Zoloft), amitriptyline (Elavil), clomipramine (Anafranil), imipramine (Tofranil), sumatriptan (Imitrex), zolmitriptan (Zomig), rizatriptan (Maxalt), methadone (Dolophine), tramadol (Ultram) is not recommended.

Medications for diabetes: May lower blood sugar levels. This could interfere with medications used for diabetes and cause blood sugar levels to go too low. If you have diabetes, monitor your blood sugar closely.

Antihypertensive drugs: BIOGEN NIGHT BURN might decrease blood pressure. This could cause blood pressure to go too low in people with low blood pressure; or interfere with medications used to treat high blood pressure. BIOGEN NIGHT BURN should be used cautiously if you have low blood pressure or take medications for your blood pressure.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. BIOGEN NIGHT BURN is not indicated for use during pregnancy or lactation. Consult a health care provider prior to use if you are of childbearing age, pregnant or breastfeeding.

Do not use BIOGEN NIGHT BURN while pregnant or breastfeeding (see section 4.3).

4.7 Effects on ability to drive and use machines

BIOGEN NIGHT BURN is unlikely to affect the ability to drive a vehicle or use machines. Caution is advised not to drive a vehicle or operate machinery until the effects of BIOGEN NIGHT BURN are known.

4.8 Undesirable effects

BIOGEN NIGHT BURN is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Nervous system disorders:

Frequency unknown: headache, lightheadedness, dizziness, drowsiness.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: brief periods of breathlessness.

Gastrointestinal disorders:

Frequency unknown: heartburn, stomach pain, belching and flatulence, nausea, vomiting, dry mouth

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

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
Category and class:

Category D 33.7 Combination product. Complementary Medicine

A combination of active ingredients providing a night time supplement to support active individuals. InnoSlim for weight and metabolic support through reduced glucose absorption in the intestine, increased glucose absorption in muscle and fat cells, reduced fat accumulation and inflammation in fat cells, and reduced insulin resistance. Ashwagandha contains withanolides works by possibly suppressing stress-induced increases of dopamine receptors in the brain. L-Tryptophan, an amino acid which is able to cross the blood-brain barrier where it has sedative effects. Theanine, an amino acid with relaxing and anti-anxiety effects.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Vegicapsule
Magnesium stearate
Aerosil (Silicon dioxide)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 °C. Protect from moisture.

6.5 Nature and contents of container

PET container (250 mL) with a Red Biogen PET screw cap.
Pack size: 60 vegicapsules.
Including a 65 mm x 10 mm round foam wad and a 0.5 g silica bag.

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

This leaflet was last revised in November 2020.

JOB: BSF_Biogen Night Burn_60s		SIZE: 210mm x 370mm	
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"/> Available Slot	<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"/> Spot UV	<input type="checkbox"/> Dornig	<input type="checkbox"/> Embossing	

