

PROFESSIONAL INFORMATION
D 33.7 Combination product. Complementary medicine.

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE
 BIOGEN THERMO BURN capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

| | | %NRV* |
|--|-----------|-------|
| Sinetrol® Xpur (standardised citrus and guarana extracts) | 225,00 mg | |
| from: <i>Citrus grandis</i> (L.) Osbeck (Grapefruit) | 101,25 mg | |
| [fruit extract] | | |
| <i>Paullinia cupana</i> Kunth (Guarana) | 22,50 mg | |
| [seed extract] | | |
| <i>Citrus sinensis</i> (L.) Osbeck (Sweet orange) | 22,50 mg | |
| [fruit extract] | | |
| <i>Citrus sinensis</i> (L.) Osbeck (Blood orange) | 11,25 mg | |
| [fruit concentrate] | | |
| Total Caffeine | 50,00 mg | |
| from: Caffeine Anhydrous | 44,38 mg | |
| Sinetrol® Xpur | 5,62 mg | |
| L-Theanine | 50,00 mg | |
| Betaine Hydrochloride | 45,00 mg | |
| <i>Rhodiola rosea</i> L. (Arctic root) | 36,25 mg | |
| [Root, extract standardised to 3 % Salidroside] | | |
| Pyridoxine (Vitamin B6) (from Pyridoxine Hydrochloride) | 5,00 mg | 100 % |
| BioPerine® Piper nigrum L. (Black pepper) | 2,50 mg | |
| [Fruit, 50:1 extract standardised to 95 % piperine providing 62,50 mg DHE] | | |
| Vitamin B12 (Cyanocobalamin) | 12,50 µg | 521% |
| Chromium (from Chromium Picolinate) | 12,50 µg | 36% |
| Sugar free | | |

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetable capsules.
 Size 00 white vegetable capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN THERMO BURN is indicated as an aid to a weight management programme, in conjunction with a balanced diet and exercise program.

4.2 Posology and method of administration
Adults:

Take 2 capsules twice daily, at least 30 minutes before meals or snacks (preferably with breakfast and lunch). If you are training early in the morning, take 2 capsules before your workout and consume a post-workout meal directly after training, or as recommended by your health care provider. Consumption not recommended after 16:00. Consume for 5 consecutive days and take a 2 day break before resuming again.

Do not exceed the recommended dosage.

Elderly:

No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

Patient with impaired renal and/or liver function:

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

Children and adolescents:

Not recommended in children and adolescents below the age of 18 years (see section 4.4).

4.3 Contraindications

- If you have a hypersensitivity to Grapefruit extract, Guarana, Sweet orange extract, Blood orange extract, Caffeine anhydrous, L-theanine, Betaine HCl, Rhodiola rosea, Vitamin B6, BioPerine, Vitamin B12 and Chromium or any of the excipients listed in 6.1.
- Consult a healthcare provider prior to use if you are pregnant, breastfeeding or have a kidney disorder.
- Consult a healthcare provider prior to use if you are taking other diuretics.
- Not recommended for use in children under the age of 18 years.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN THERMO BURN.
 If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant, breastfeeding or have a kidney disorder.
- Consult a healthcare provider prior to use if you are taking other diuretics.
- CONTAINS CAFFEINE. Not suitable for children under the age of 18 years.
- Not intended as a substitute for sleep.
- Hypertension, glaucoma and/or detrusor instability (overactive bladder syndrome).
- Consult a health care provider prior to use if you have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome). The caffeine content may increase high blood pressure, increase intraocular pressure, and/or worsen symptoms of incontinence (such as urinary frequency and urgency).
- May reduce blood flow to the heart muscle during exercise, which might lead to cardiovascular complications such as chest pain and irregular heartbeat.
- Patients are advised to discontinue BIOGEN THERMO BURN at least 2 weeks prior to any surgical procedures.
- Might affect blood glucose levels, which might interfere with blood glucose control in patients with diabetes mellitus (see section 4.5).
- Caution is advised for patients with existing renal or liver impairment.
- Patients with epilepsy should use BIOGEN THERMO BURN with caution.
- Avoid taking with health products or foods that contain caffeine and/or increase blood pressure (e.g. medications, coffee, tea, colas, cocoa, guarana, mate, bitter orange extract, synephrine, octopamine, ephedra, ephedrine).
- Caffeine has been shown to reduce blood flow to the heart muscle during exercise which might lead to cardiovascular complications such as chest pain, and irregular heartbeat even in healthy individuals. If those symptoms occur, stop use and consult a health care practitioner/health care provider.
- Patients who have early Leber's disease (hereditary optic nerve atrophy) have been found to suffer severe and swift optic atrophy when Vitamin B12 is administered.
- Treatment of severe Vitamin B12 megaloblastic anemia may result in severe hypokalemia.
- Vitamin B6 might increase the photosensitivity caused by amiodarone, have additive effects when used with antihypertensive drugs, may increase the metabolism of levodopa when taken alone, but not when taken in conjunction with carbidopa. Vitamin B6 may reduce the levels and clinical effects of phenobarbital and phenytoin.
- Vitamin B12 is not a substitute for folic acid and since it might improve folic acid deficient megaloblastic anemia, unselective use of vitamin B12 could mask the true diagnosis.
- Antibiotics (used to treat infections) and antimetabolites (used to treat some cancers) can affect the blood tests to measure Vitamin B12.
- Colchicine, aminoglycosides, certain anticonvulsants (e.g., phenytoin, Phenobarbital, primidone), para-aminosalicylic acid or excessive alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B12. Vitamin C may destroy Vitamin B12. Patients are advised to avoid ingesting large amounts of Vitamin C within 1 hour of oral Vitamin B12 administration.

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

No specific drug interaction studies have been performed on BIOGEN THERMO BURN, however, the pharmacokinetic properties of Grapefruit extract, Guarana, Sweet orange extract, Blood orange extract, Caffeine anhydrous, L-theanine, Betaine HCl, Rhodiola rosea, Vitamin B6, BioPerine, Vitamin B12 and Chromium have been summarized.

Interactions with Medicines

- Consult a health care provider prior to use if you are taking lithium.
- Consumption with other medicines which increase blood pressure (e.g. bitter orange extract, synephrine, octopamine, ephedra, ephedrine) is not recommended.
- Consumption with other caffeine-containing products (e.g. medicines, coffee, tea, colas, cocoa, guarana, maté) is not recommended.
- May potentiate effects of oral hypoglycaemics and may reduce insulin requirement, increasing the risk of hypoglycemia. Dose adjustment of diabetic medicines and glucose monitoring may be necessary.
- Anticonvulsant medicines (such as carbamazepine, ethosuximide, felbamate, phenobarbital, phenytoin or valproate) as in BIOGEN THERMO BURN may decrease the effects of anticonvulsants and increase the risk of seizures.
- BIOGEN THERMO BURN may increase the risk of bleeding when used concomitantly with anticoagulant medicines (such as heparin or warfarin) or antiplatelet medicines (such as aspirin, clopidogrel, dipyridamole or ticlopidine).
- Concomitant use of Rhodiola with anti-diabetic drugs might increase the risk of hypoglycemia, Rhodiola extract can decrease blood glucose due to alpha-glucosidase activity.
- Rhodiola extract inhibits angiotensin-converting enzyme (ACE) and might lower blood pressure, taking Rhodiola with antihypertensive drugs might increase the risk of hypotension.
- Rhodiola inhibits CYP1A2 and CYP2C9, and might increase levels of drug metabolized by CYP1A2 and CYP2C9.
- Rhodiola has immunostimulatory effects, and might interfere with immunosuppressive therapy, and might increase the levels and adverse effects of losartan.
- Rhodiola inhibits P-glycoprotein, and might increase levels of P-glycoprotein substrates.
- Theanine might lower blood pressure, potentiating the effects of antihypertensive drugs. Concomitant use of theanine and antihypertensive drugs might potentiate the antihypertensive activity.

Interactions with Diseases / Impairments

- Patients are advised to discontinue BIOGEN THERMO BURN at least 2 weeks before elective surgical procedures (see section 4.4).
- BIOGEN THERMO BURN and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).
- B vitamins might increase the rate of restenosis after bare metal stent placement.
- Rhodiola might exacerbate certain autoimmune diseases by stimulating disease activity; avoid use or use with caution in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others. Rhodiola might have immunostimulatory effects.
- B vitamins might increase the rate of restenosis after bare metal stent placement.
- Supplemental vitamin B6 at levels above the dietary reference intakes (DRI) should not be recommended following bariatric surgery.
- Hypokalemia and thrombocytosis could occur upon conversion of severe megaloblastic to normal erythropoiesis with Vitamin B12 therapy. Therefore, serum potassium levels and the platelet count should be monitored carefully during oral administration.
- Vitamin B12 deficiency may suppress the signs of polycythemia vera.

Interactions with Foods

Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN THERMO BURN.
 • Alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B12

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

BIOGEN THERMO 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.

4.7 Effects on ability to drive and use machines

BIOGEN THERMO 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 THERMO BURN are known.

4.8 Undesirable effects

BIOGEN THERMO BURN is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity/allergy is known to occur, in which case, discontinue use. Caffeine can cause anaphylaxis in sensitive individuals, although true IgE-mediated caffeine allergy seems to be relatively rare.

Psychiatric disorders:

Frequency unknown: anxiety, agitation, irritability, mood changes.

Nervous system disorders:

Frequency unknown: insomnia, nervousness, restlessness, tremors, convulsions, headache, sleep disturbances. Rhodiola extract can cause dizziness. Vitamin B6 (pyridoxine) can cause headache, paresthesia, and somnolence.

Ear and labyrinth disorders:

Frequency unknown: ringing sound in the ears.

Cardiac disorders:

Frequency unknown: tachycardia, chest pain, dysrhythmia.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: quickened respiration, tachypnea-induced respiratory alkalosis.

Gastrointestinal disorders:

Frequency unknown: temporary gastric irritation, nausea, vomiting.

Renal and urinary disorders:

Frequency unknown: diuresis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BIOGEN THERMO BURN is important. It allows continued monitoring of the benefit/risk balance of BIOGEN THERMO BURN Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://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
5.1 Pharmacodynamic properties
Mechanism of action

Grapefruit seed extract grapefruit flavonoids have demonstrated activity as catalysts of lipolysis, breaking down triglycerides stored in fat cells and stimulating the release of fatty acids and glycerol.

Guarana acts as a central nervous system (CNS) stimulant. Caffeine, the main constituent of guarana, increases resting energy expenditure (REE) and cellular thermogenesis. It also causes an increase in nonoxidative fatty acid turnover and lipid oxidation; however, the net effect on lipid oxidation is small. The effects of caffeine on energy expenditure and lipid metabolism seem to be mediated by both sympathetic and nonsympathetic mechanisms.

Citrus bioflavonoids are a source of antioxidants.

Caffeine anhydrous, increases resting energy expenditure (REE) or resting metabolic rate (RMR), and cellular thermogenesis.

Rhodiola, *Rhodiola* contains over 30 compounds including phenylethanoids, phenylpropanoids, flavonoids, cyanoglycosides, monoterpenes, and triterpenes. The phenylpropanoid glycoside called salidroside, rhodioloside, or rhodosine is thought to be responsible for many of the stimulant or "adaptogenic" effects of rhodiola. *L-theanine*, Theanine is an amino acid which may promote weight loss effects.

Vitamin B6, required for amino acid metabolism. It is also involved in carbohydrate and lipid metabolism. In the body, vitamin B6 is converted to the coenzyme pyridoxal phosphate for a wide variety of metabolic reactions. These reactions include transamination of amino acids, conversion of tryptophan to niacin, synthesis of gamma-aminobutyric acid (GABA) in the CNS, metabolism of serotonin, norepinephrine and dopamine, metabolism of polyunsaturated fatty acids and phospholipids, and the synthesis of the heme component of hemoglobin.

Vitamin B12 is essential to growth, cell reproduction, hematopoiesis, and nucleoprotein and myelin synthesis. Cells characterized by rapid division (e.g., epithelial cells, bone marrow, myeloid cells) appear to have the greatest requirement for vitamin B12. Vitamin B12 can be converted to coenzyme B12 in tissues, and as such is essential for conversion of methylmalonate to succinate and synthesis of methionine from homocysteine, a reaction which also requires folate.

Black pepper/BioPerine is a patented, standardised extract from black pepper containing 95% piperine (a bioavailability enhancer for nutrients). Used in combination with other ingredients it may enhance the uptake and utilisation of the natural actives increasing the bioavailability of supplemented nutrients through increased absorption.

Chromium potentiates the action of insulin and thus influences carbohydrate, fat and protein metabolism.

Pharmacodynamic effects:

Grapefruit seed extract, Flavonoid-induced lipolysis occurs through inhibition of cAMP-phosphodiesterase and maintenance of lipolysis-inducing cAMP levels. Stimulation of adipose tissue lipolysis may upregulate the use of lipid energy by the body.

Guarana, Caffeine is often used in combination with ephedra for weight loss and seems to have additive pharmacodynamic effects.

Citrus bioflavonoids, The flavonoid constituents naringin and nobiletin, found in sweet orange, might have anti-inflammatory activity.

Caffeine anhydrous, The thermogenic effects of caffeine may be due to vasoconstriction and increase in vascular smooth muscle tone.

Rhodiola, *Rhodiola root extract* appears to inhibit the activity of monoamine oxidase B (MAOB) *in vitro*, which suggests that it may have protective effects against MAOB-related neurodegenerative diseases.

L-theanine, L-theanine may act synergistically with caffeine and other constituents in green tea to cause weight loss.

Vitamin B6, supplementation might also be useful for some dysphoric mental states because it increases the production of serotonin and GABA.

Vitamin B12 In humans; exogenous source of vitamin B12 is required for nucleoprotein and myelin synthesis, cell production, normal growth, and for the maintenance of normal erythropoiesis.

Black pepper/ BioPerine: As a thermo nutrient BioPerine® would potentially improve the process of nutrient absorption by enhancing thermogenesis. Most of the food or nutrient-induced thermogenesis is facilitated by beta receptors, which include a compound known as cyclic adenosine 3',5' monophosphate (cAMP). The role of cAMP as a "second messenger" to the hormonal and enzymatic actions in the body is well recognized. Piperine has been found in independent studies to stimulate the release of catecholamines, thermogenic hormones whose action is made possible by the presence of cAMP. Other mechanisms by which piperine stimulate nutrient absorption has also been discussed in literature. These include increased micelle formation, stimulation of active transport of amino acids (gamma-glutamyl transpeptidase), and epithelial cell wall modification due to the affinity of piperine towards fats and fatty substances.

Chromium, may induce these effects by affecting the brain's hunger receptors. Some research suggests that chromium might sensitize insulin-sensitive glucoreceptors in the brain, resulting in appetite suppression, activation of the sympathetic nervous system, stimulation of thermogenesis, and down-regulation of insulin secretion.

5.2 Pharmacokinetic properties
Absorption/Distribution/Metabolism/Excretion
Grapefruit seed extract.

There is insufficient reliable information available about the pharmacokinetics of grapefruit seed extract.

Guarana

There is insufficient reliable information available about the pharmacokinetics of guarana.

Citrus bioflavonoids.

There is insufficient reliable information available about the pharmacokinetics of citrus bioflavonoids.

Caffeine anhydrous.

Absorption: Caffeine is rapidly and almost completely (99%) absorbed from the gut after ingestion. Peak levels in the circulation typically occur 30-60 minutes after ingestion.

Distribution: Caffeine is widely distributed throughout the tissues of the body after oral, rectal, or parenteral administration. It crosses the blood-brain barrier, so effects are exerted both centrally and peripherally.

Metabolism: Caffeine is metabolized in the liver by cytochrome P450 1A2 (CYP1A2) enzymes to paraxanthine (84%), theophylline (4%), and theobromine (12%).

Excretion: The half-life of caffeine in healthy adults is 1.5-10 hours and is decreased by smoking.

Rhodiola, The bioavailability of salidroside, a constituent of rhodiola, was 32.1%.

Excretion: When administered at a dose of 12 mg/kg, the mean residence time of salidroside was 41.7 minutes when given orally and 17.9 minutes.

L-theanine.

Absorption: Theanine is absorbed through the intestines. The peak concentration of L-theanine in the plasma occurs at about 50 minutes after oral intake.

Distribution: Following absorption, L-theanine is distributed to the plasma and erythrocytes. L-theanine can cross the blood brain barrier and appears to do so in a dose-dependent manner.

Metabolism: L-theanine is hydrolyzed in the intestines to ethylamine and glutamic acid.

Excretion: A small amount of L-theanine is retained in erythrocytes, but most L-theanine and its metabolites are excreted in the urine 3-24 hours after oral intake.

Vitamin B6, is absorbed passively in the upper gastrointestinal tract.

Metabolism: In the liver, vitamin B6 is converted to the coenzyme pyridoxal phosphate.

Excretion: Vitamin B6 metabolites are excreted in the urine.

Vitamin B12 is irregularly absorbed from the distal small intestine following oral administration. Vitamin B12 absorption is an active process that requires gastric intrinsic factor. Intrinsic factor is a glycoprotein secreted by the gastric mucosa. Passive diffusion through the intestinal wall can occur but large amounts of B12 are required (i.e. >1 mg). Following oral doses less than 3 mcg, peak plasma concentrations are not reached for 8 to 12 hours because the vitamin is transiently retained in the wall of the lower ileum.

Distribution: Vitamin B12 is distributed into the liver, bone marrow, and other tissues, including the placenta. At birth, the blood concentration of vitamin B12 in neonates is 3 to 5 times that of the mother. Total body stores of vitamin B12 in healthy individuals are estimated to range from 1 to 11 mg, with an average of 5 mg; 50 to 90 % is stored in the liver. Vitamin B12 is believed to be converted to coenzyme form in the liver and is probably stored in tissues in this form.

Metabolism: Vitamin B12 is converted in tissues to active coenzymes, methylcobalamin and deoxyadenosylcobalamin; undergoes some enterohepatic recycling.

Excretion: About 3-8 mcg of B12 is secreted into the GI tract daily via the bile; in normal subjects with sufficient intrinsic factor, all but about 1 mcg is reabsorbed. When B12 is administered in doses which saturate the binding capacity of plasma proteins and the liver, the unbound B12 is rapidly eliminated in the urine. Retention of B12 in the body is dose-dependent.

Black pepper/BioPerine: There is insufficient reliable information available about the pharmacokinetics of black pepper.

Chromium, Absorption: When ingested, most chromium is excreted unabsorbed in the feces.

Distribution: After absorption, chromium is bound to transferrin. The distribution may occur across fast, medium, and slow compartments, with serum chromium not in equilibrium with tissue-organ stores.

Excretion: The small percentage of chromium that is absorbed is rapidly excreted in the urine.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Aerosil.
 Magnesium stearate.
 Potato starch.
 Vegetable capsule (containing hypromellose).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C. Protect from moisture.
 Keep in the original container until required for use.

6.5 Nature and contents of container

Black PET container (250 mL) with a black Biogen PET lid. Packed in a unit carton.
 Pack size: 80 vegetable capsules.

6.6 Special precautions for disposal and other handling

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/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

| | | | |
|---|---|---|---|
| JOB: BR5_Slimfit Thermo_Burn_80s | | SIZE: 210mm x 461 mm | |
| 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"/> Doming | <input type="checkbox"/> Embossing | |

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **[S0]**

Biogen Thermo Burn capsules

Sinetrol® Xpur (standardised citrus and guarana extracts), Caffeine anhydrous, L-theanine, Betaine HCl, Rhodiola rosea, Vitamin B6, BioPerine, Vitamin B12 and Chromium
Sugar free.

D 33.7 Combination product. Complementary medicine.
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 Thermo Burn capsules are available without a doctor's prescription. Nevertheless, you still need to take Biogen Thermo Burn capsules 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.

What is in this leaflet

1. What Biogen Thermo Burn is and what it is used for.
2. What you need to know before you take Biogen Thermo Burn.
3. How to take Biogen Thermo Burn.
4. Possible side effects.
5. How to store Biogen Thermo Burn.
6. Contents of the pack and other information.

1. What Biogen Rage Thermo is and what it is used for

Biogen Thermo Burn is a health supplement which contains Sinetrol® Xpur (standardised citrus and guarana extracts), Caffeine anhydrous, L-theanine, Betaine HCl, Rhodiola rosea, Vitamin B6, BioPerine, Vitamin B12 and Chromium.

Biogen Thermo Burn is used as an aid to a weight management programme, in conjunction with a balanced diet and exercise program.

2. What you need to know before you take Biogen Thermo Burn

Do not take Biogen Thermo Burn:

- If you are hypersensitive (allergic) to any active or inactive ingredient in Biogen Thermo Burn (see what Biogen Thermo Burn contains).

Warnings and precautions

CONTAINS CAFFEINE. Do not use in children under the age of 18 years.

Do not use Biogen Thermo Burn as a substitute for sleep.

Take special care with Biogen Thermo Burn:

- If you have high blood pressure.
- If you have glaucoma (increased pressure in the fluid in your eye).
- If you have overactive bladder syndrome (involuntary loss of urine).
- If you have any heart condition, such as chest pain or irregular heartbeat.
- If you have a bleeding disorder (you must discontinue Biogen Thermo Burn at least 2 weeks prior to any surgical procedures).
- If you are diabetic and you are taking medicines to control your blood sugar levels.
- If you have an existing liver disease (yellow skin and eyes) or if your kidneys are not functioning normally (less urine than is normal for you).
- If you suffer from epilepsy (seizures).

Other medicines and Biogen Thermo Burn

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines.

Tell your doctor or pharmacist if you are currently using:

- Lithium (used to treat bipolar disorder).
- Bitter orange extract, synephrine, octopamine, ephedra or ephedrine (used as weight loss supplements or to enhance athletic performance).
- Caffeine-containing products (e.g. medicines, coffee, tea, colas, cocoa, guarana, maté).
- Insulin or oral hypoglycaemic medicines (used to treat diabetes (high blood sugar)).
- Anticonvulsant medicines, such as carbamazepine, ethosuximide, felbamate, phenobarbital, phenytoin or valproate (used to treat epilepsy (seizures/fits)).
- Anticoagulant medicines (such as heparin or warfarin) or antiplatelet medicines (such as aspirin, clopidogrel, dipyridamol, ticlopidine) used to prevent the forming of blood clots.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking Biogen Thermo Burn.

Safety and efficacy of Biogen Thermo Burn during pregnancy and lactation have not been established. Do not use Biogen Thermo Burn if you are pregnant or breastfeeding.

Driving and using machinery

Biogen Thermo Burn is unlikely to have an effect on your ability to drive a vehicle or use machines. Caution is advised until you know how Biogen Thermo Burn affects you.

3. How to take Biogen Thermo Burn

Do not share medicines that was prescribed to you with any other person. Do not exceed the recommended daily dose. Use **Biogen Rage Thermo Extreme** exactly as recommended in this pamphlet, or as recommended by your healthcare practitioner. Consult your doctor or pharmacist if you are unsure.

Adults 18:

Take 2 capsules twice daily, at least 30 minutes before meals or snacks (preferably with breakfast and lunch). If you are training early in the morning, take 2 capsules before your workout and consume a post-workout meal directly after training, or as recommended by your health care provider. Consumption not recommended after 16:00. Consume for 5 consecutive days and take a 2 day break before resuming.

Do not exceed the recommended dosage.

If you take more Biogen Thermo Burn than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining **Biogen Thermo Burn** vegetable capsules with you so the doctor will know what you have taken.

4. Possible side effects

Biogen Thermo Burn can have side effects.

Not all side effects reported for Biogen Thermo Burn are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Biogen Thermo Burn, please consult your health care provider for advice.

If any of the following happens, stop taking Biogen Thermo Burn and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Biogen Thermo Burn. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

Side effects occurring with unknown frequency:

- Fast, irregular or abnormal heartbeat, chest pain.
- Rapid shallow breathing.

Tell your doctor as soon as possible if you notice any of the following:

Side effects occurring with unknown frequency:

- Anxiety, agitation, irritability, mood changes.
- Sleeping problems, feeling nervous, restless, tremors (shaking), convulsions (seizures/fits), headache.
- Ringing sound in your ears.
- Irritation in the stomach area (temporarily), nausea (feeling sick), vomiting (being sick).
- Increased urine production and the frequency you need to urinate.

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

By reporting side effects, you can help provide more information on the safety of Biogen Thermo Burn.

5. How to store Biogen Thermo Burn

- Store at or below 25 °C. Protect from moisture.
- Keep in the original container until required for use.
- 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 Rage Thermo Extreme contains

| Each vegetarian capsule contains: | | %NRV* |
|---|-----------|-------|
| Sinetrol® Xpur (standardised citrus and guarana extracts) | 225,00 mg | |
| from: <i>Citrus grandis</i> (L.) Osbeck (Grapefruit) [fruit extract] | 101,25 mg | |
| <i>Paullinia cupana</i> Kunth (Guarana) [seed extract] | 22,50 mg | |
| <i>Citrus sinensis</i> (L.) Osbeck (Sweet orange) [fruit extract] | 22,50 mg | |
| <i>Citrus sinensis</i> (L.) Osbeck (Blood orange) [fruit concentrate] | 11,25 mg | |
| Total Caffeine | 50,00 mg | |
| from: Caffeine Anhydrous | 44,38 mg | |
| Sinetrol® Xpur | 5,62 mg | |
| L-Theanine | 50,00 mg | |
| Betaine Hydrochloride | 45,00 mg | |
| <i>Rhodiola rosea</i> L. (Arctic root) [Root, extract standardised to 3 % Salidroside] | 36,25 mg | |
| Pyridoxine (Vitamin B6) (from Pyridoxine Hydrochloride) | 5,00 mg | 100 % |
| BioPerine® <i>Piper nigrum</i> L. (Black pepper) [Fruit, 50:1 extract standardised to 95 % piperine providing 62,50 mg DHE] | 2,50 mg | |
| Vitamin B12 (Cyanocobalamin) | 12,50 µg | 521 % |
| Chromium (from Chromium Picolinate) | 12,50 µg | 36 % |

The other ingredients are aerosil, magnesium stearate, potato starch and vegetable capsules (containing hypromellose).

What Biogen Thermo Burn looks like and contents of the pack

Size 00 white vegetarian capsules.
White PET container (50 ml) with a Biogen PET lid. Packed in a unit carton.
Pack size: 80 vegetable capsules.

Holder of certificate of registration

Biogen
23 Stag Road, Glen Austin, South Africa
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This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to corresponding Professional Information

www.biogen.co.za

PASİENTİN LİGİTİNGSBLAD

SKEDULERİNGSTATUS: **[S0]**

Biogen Thermo Burn kapsules

Sinetrol® Xpur (gestandaardiseerde sitrus- en guarana-ekstrakte), Anhidriese kaffeien, L-teanien, Betaienhidrochloried, Rhodiola rosea, Vitamien B6, BioPerine, Vitamien B12 en Chroom.

Suikervry

KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING / WESTERSE KRUIEMEDISYNE
Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Lees hierdie inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.
Biogen Thermo Burn kapsules is beskikbaar sonder 'n dokter se voorskryf. Biogen Thermo Burn kapsules nietermin steeds versigtig neem om die beste resultate te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie pamflet

1. Wat is Biogen Thermo Burn en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy Biogen Thermo Burn neem.
3. Hoe om Biogen Thermo Burn te neem.
4. Moontlike newe-effekte.
5. Hoe om Biogen Thermo Burn te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is Biogen Thermo Burn en waarvoor word dit gebruik

Biogen Thermo Burn is 'n gesondheidsaanvulling wat Sinetrol® Xpur (gestandaardiseerde sitrus- en guarana-ekstrakte), Anhidriese kaffeien, erba mate, Olyf blaar ekstrak, L-teanien, Vitamien B6, BioPerine, en Chroom.

Biogen Thermo Burn word gebruik as hulpmiddel in 'n gewigsbestuurprogram, saam met 'n gebalanseerde dieet en oefenprogram.

2. Wat jy moet weet voordat jy Biogen Thermo Burn neem

Moenie Biogen Rage Thermo Extreme neem nie:

- Indien jy hipersensitief (allergies) is vir enige van die aktiewe of onaktiewe bestanddele in Biogen Thermo Burn (sien wat Biogen Thermo Burn bevat).

Waarskuwings en voorsorgmaatreëls

BEVAT KAFFEÏEN. Kinders jonger as 18 jaar moet dit nie gebruik nie.

Moenie Biogen Thermo Burn as 'n plaasvervanger vir slaap gebruik nie.

Wees versigtig met Biogen Thermo Burn:

- Indien jy hoë bloeddruk het.
- Indien jy gloukoom het (verhoogde druk in die vog in jou oog).
- Indien jy aan ooraktiewe blaasindroom ly (onwillekeurige urienlating).
- Indien jy enige harttoestand het, soos pyn in die bors of onreëlmatige hartklop.
- Indien jy 'n bloedingafwyking het (jy moet ten minste twee weke voor enige chirurgiese prosedure ophou om Biogen Thermo Burn te gebruik).
- Indien jy 'n diabeet is en medisyne neem om jou bloedsuikervlakke te beheer.
- Indien jy aan 'n bestaande lewersiekte ly (geel vel en oë) of indien jou niere nie normaal funksioneer nie (produseer minder urine as wat normaal is vir jou).
- Indien jy aan epilepsie (toevalle) ly.

Ander medisyne en Biogen Thermo Burn

Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem. Dit sluit komplementêre of tradisionele medisyne in.

Sê vir jou dokter of apteker indien jy tans enige van die volgende gebruik:

- Litium (gebruik om bipolêre versteuring te behandel).
- Bitterlemoeneekstrak, sinefrien, oktopamien, efedra of efedrien (gebruik as aanvullings om gewig te verloor of om atletiese prestasie te bevorder).
- Produkte wat kaffeien bevat (bv. medisyne, koffie, tee, koladranksies, kakao, guarana, maté).
- Insulien of mondelike hipoglisemiese medisyne (gebruik om diabetes [hoë bloedsuiker] te behandel).
- Antikonvulsantmedisyne, soos karbamasepien, etosuksimid, felbamaat, fenobarbitaal, fenitoin of valproaat (gebruik om epilepsie [toevalle] te behandel).
- Antistomiddels (soos heparien of warfarin) of antiplaatjemedisyne (soos aspirien, klopidogrel, dipiridamol, tiklopidien) wat gebruik word om te verhoed dat bloedklonte vorm.

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy Biogen Thermo Burn neem.

Dit is nie vasgestel of Biogen Thermo Burn veilig en effektief tydens swangerskap en borsvoeding is nie. Moenie Biogen Thermo Burn neem indien jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjinerie

Dit is onwaarskynlik dat Biogen Thermo Burn 'n uitwerking op jou vermoë om 'n voertuig te bestuur of masjinerie te gebruik sal hê. Wees versigtig totdat jy weet hoe Biogen Thermo Burn jou affekteer.

3. Hoe om Biogen Thermo Burn te neem

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik Biogen Thermo Burn presies soos aanbeveel in hierdie pamflet, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u dokter of apteker indien u onseker is.

Volwassenes 18:

Neem 2 kapsules twee keer daaglik, minstens 30 minute voor etes of versnaperinge (verkieslik saam met ontbyt en middagete). Indien jy vroegoggend oefen, neem 2 kapsules voor jou oefensessie en eet 'n maaltyd direk na die oefensessie, of soos deur jou gesondheidsorgverskaffer aanbeveel. Verbruik na 16:00 word nie aanbeveel nie. Gebruik vir 5 agtereenvolgende dae en neem dan 'n breek van 2 dae voordat jy weer aangaan.

Moenie die aanbevole dosis oorskry nie.

Wat om te doen indien jy meer Biogen Thermo Burn geneem het as wat jy moet

In geval van oordosering, konsulteer jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die houer met die oorblywende Biogen Thermo Burn kapsules saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike newe-effekte

Biogen Thermo Burn kan newe-effekte hê.

Nie alle newe-effekte wat vir Biogen Thermo Burn gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind tervyl jy Biogen Thermo Burn neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om Biogen Thermo Burn te neem en sê dadelik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling.
- Uitslag of gejeuk.
- Floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op Biogen Thermo Burn gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê onmiddellik vir jou dokter indien jy enige van die volgende opmerk:

Neuwe-effekte wat met onbekende frekwensie voorkom:

- Vinnige, onreëlmatige of abnormale hartklop, borskaspyen.
- Vinnige vlak asemhaling.

Sê so gou as moontlik vir jou dokter indien jy enige van die volgende opmerk:

Neuwe-effekte wat met onbekende frekwensie voorkom:

- Angstigheid, agitatie, prikkelbaarheid, wisselende buie.
- Slaapprobleme, sensuueagtigheid, rusteloosheid, tremors (bewe/ruk), konvulsies (toevalle), hoofpyn.
- Gesuis in jou ore.
- Irritasie in die omgewing van die maag (tydelik), naardeit, braking.
- Toename in produksie van urine en die frekwensie wat u die behoefte het om te urineer.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **"6.04 Adverse Drug Reactions Reporting Form"**, wat aanlyn by SAHPRA se publikasies beskikbaar is: <https://www.sahpra.org.za/Publications/Index/8>.

Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van Biogen Thermo Burn te verskaf.

5. Hoe om Biogen Thermo Burn te bêre

- Bêre by of onder 25 °C. Beskerm teen vog.
- Hou in die oorspronklike houer tot nodig vir gebruik.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik na die vervaldatum wat op die houer gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioelstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

| Wat Biogen Thermo Burn bevat | | %NRV* |
|---|-----------|-------|
| Elke vegetariese kapsule bevat: | | |
| Sinetrol® Xpur (gestandaardiseerde sitrus- en guarana-ekstrakte) | 225,00 mg | |
| uit: <i>Citrus grandis</i> (L.) Osbeck (Pomelo) [vrug, ekstrak] | 101,25 mg | |
| <i>Paullinia cupana</i> Kunth (Guarana) [saad, ekstrak] | 22,50 mg | |
| <i>Citrus sinensis</i> (L.) Osbeck (Soetlemoen) [vrug, ekstrak] | 22,50 mg | |
| <i>Citrus sinensis</i> (L.) Osbeck (Bloedlemoen) [vrug, konsentraat] | 11,25 mg | |
| Totale Kaffeien | 50,00 mg | |
| uit: Anhidriese kaffeien | 44,38 mg | |
| Sinetrol® Xpur | 5,62 mg | |
| L-Theanien | 50,00 mg | |
| <i>Betaienhidrochloried</i> | 45,00 mg | |
| Rhodiola rosea L. (Arctic root) [Root, extract standardised to 3 % Salidroside] | 36,25 mg | |
| Pyridoksien (Vitamin B6) (van Piridoksienhidrochloried) | 5,00 mg | 46 % |
| BioPerine® <i>Piper nigrum</i> L. (Swartpeper) [Vrug, 50:1 ekstrak gestandaardiseer tot 95 % piperine wat 62,50 mg DHE verskaf] | 2,50 mg | |
| Vitamien B12 (Sianokobalamin) | 12,50 µg | 521 % |
| Chroom (van Chroompikolinaat) | 12,50 µg | 36 % |

Die ander bestanddele is aerosil, magnesiumstearaat, aartappelstysel en plantaardige kapsules (bevat hipromellose).

Hoe Biogen Thermo Burn lyk en inhoud van die verpakking

Grootte 00 wit vegetariese kapsules.
Wit PET-houer (250 mL) met 'n Biogen PET-deksel.
Verpakkingsgrootte: 80 plantaardige kapsules.

Houer van die sertifikaat van registrasie

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Stagweg 23, Glen Austin, Suid Afrika
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Tel: 011 589 2322

Hierdie inligtingsblad is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

www.biogen.co.za

| | | | |
|---|--|-----------------------------|--|
| JOB: BR5_Slimfit Thero Burn_80s | | SIZE: 210mm x 461 mm | |
| 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: | | | |