

PROFESSIONAL INFORMATION

SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:



USN PHEDRACUT LAVA BURN

(powder)

COMPOSITION:

Active ingredients:

Each sachet (5 g) contains:		%NRV*
<i>Garcinia cambogia</i> extract (60 % HCA)	830 mg	
N-Acetyl-L-Carnitine	500 mg	
Total Caffeine (from Caffeine Anhydrous & Green Coffee Bean extract)	300 mg	
Calcium-HMB (Hydroxy Methyl Butyrate)	250 mg	3 %
Fucoaxanthin extract (10 %)	240 mg	
Green Coffee Bean (<i>Coffea robusta</i>) extract (45 % Chlorogenic Acid)	200 mg	
Phosphatidylserine (20 %)	150 mg	
N-Acetyl-L-Glutamine	100 mg	
Vitamin B ₃ (as Nicotinic Acid)	17 mg	106 %
Chromium (as Chromium Picolinate)	25 µg	71 %

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

Inactive ingredients: Colourants, Flavourings, Fructooligosaccharide (FOS), Malic acid, Non-nutritive sweeteners (Sucralose & Acesulfame-K).

Sugar Free
Contains Sweeteners (Sucralose 200 mg & Acesulfame-K 20 mg per 5 g)

PHARMACOLOGICAL CLASSIFICATION:

D 33.7 Combination Product

PHARMACOLOGICAL ACTION:

***Garcinia cambogia*:** Hydroxycitric acid (HCA) is the principal acid in *garcinia* fruit rind. HCA competitively inhibits the extramitochondrial enzyme adenosine triphosphate (ATP) citrate lyase, which is involved in the conversion of carbohydrate to fat (lipogenesis). Inhibition of this enzyme prevents cleavage of citrate to oxaloacetate and acetyl-CoA, limiting the availability of acetyl-CoA for lipogenesis. By this mechanism, HCA limits biosynthesis of fatty acids and cholesterol in a variety of tissues. Conversion of citrate to acetyl-CoA occurs when energy consumed exceeds the energy requirements of the body. HCA is also thought to increase rates of hepatic glycogen synthesis, which influences glucoreceptors in the liver to increase satiety.

N-Acetyl-L-Carnitine: The main function of L-carnitine in the body is to help transport long-chain fatty acids into cells, where they may be oxidised to produce energy. This can be a source of energy for the muscles, as it increases the use of fat as an energy source.

Caffeine: Caffeine increases resting energy expenditure (REE) or resting metabolic rate (RMR), and cellular thermogenesis. The thermogenic effects of caffeine may be due to vasoconstriction and increase in vascular smooth muscle tone. Caffeine also causes an increase in nonoxidative fatty acid turnover and lipid oxidation. The effects of caffeine on energy expenditure and lipid metabolism seem to be mediated by both sympathetic and non-sympathetic mechanisms.

Ca-HMB: Calcium hydroxymethylbutyrate (Ca-HMB) can assist with increasing lean body mass and strength. This may be due to HMB's partial prevention of exercise-induced proteolysis and/or muscle damage. Supplementation has been found to promote muscle growth by lowering levels of 3-methylhistidine (3-MH), creatine kinase, and lactate dehydrogenase, and to reduce muscle proteolysis. It has been suggested that HMB supplementation may have positive effects on exercise performance by increasing the onset of blood lactate accumulation (OBLA); however, the mechanism remains unelucidated. OBLA is the point at which lactic acid starts to accumulate in the muscles, and is considered to occur somewhere between 85% and 90% of maximum heart rate. By increasing OBLA, HMB may function to delay feelings of exhaustion.

Fucoaxanthin extract: The seaweed constituent fucoxanthin induces UCP1 in abdominal white adipose tissue mitochondria, resulting in fatty acid oxidation and heat production. Fucoxanthin may also improve insulin resistance, resulting in decreased blood glucose levels, perhaps by regulating cytokine secretions in white adipose tissue.

Green Coffee Bean extract: Contains high concentrations of chlorogenic acids that are known to have health benefits and to influence glucose and fat metabolism, influencing postprandial blood sugar concentration, as well as glucose tolerance, serum lipid concentration and glucose absorption from the intestine.

Phosphatidylserine: Most studies have examined its influence on cognitive and physical performance. Studies examining the weight loss effect of phosphatidylserine found that it could prevent weight gain specifically by lowering cortisol levels.

N-Acetyl-L-Glutamine: L-glutamine is an amino acid. Glutamine can help reduce body weight by increasing postprandial energy expenditure and fat oxidation. During physical stress the body consumes more glutamine than the skeletal muscle can produce. Progressive muscle breakdown (wasting) can occur as the body tries to meet glutamine requirements. Protein sparing occurs when enough proteins and amino acids are provided to prevent muscle breakdown. Glutamine has been shown to have protein sparing effects.

Nicotinic acid: Nicotinic acid (Vitamin B₃) helps to metabolise carbohydrates, fats and proteins.

Chromium: Contributes to the maintenance of normal blood glucose levels. Chromium's mechanism for decreasing insulin resistance is due to an improved first phase of secretion of insulin or facilitated post-receptor insulin sensitivity as a way of potentiating the action of insulin. In addition, it has been demonstrated that chromium enhances the action of insulin at adipocyte level by increasing intracellular triglyceride synthesis and decreasing extracellular lipids.

INDICATIONS:

USN PHEDRACUT LAVA BURN is indicated as an aid to a weight management programme that includes an energy-restricted diet and regular exercise, as a thermogenic agent.

CONTRAINDICATIONS:

This product is contraindicated for individuals that are hypersensitive (allergic) to any of the listed ingredients.

Avoid in patients with liver disease. *Garcinia* might worsen liver damage in patients with existing liver disease.

Chromium might exacerbate renal disease. Avoid in patients with renal dysfunction.

Do not use if you are pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS:

- Use with caution in patients with hypertension. Caffeine can increase blood pressure.

- Use with caution in patients with long QT syndrome, as caffeine might prolong the QT interval in some patients and therefore increase the risk of ventricular arrhythmia.

- USN PHEDRACUT LAVA BURN** can increase the heart rate due to the caffeine content. It can cause tachyarrhythmia in healthy individuals and might worsen symptoms in patients already suffering from tachyarrhythmia.

- Discontinue at least two weeks before elective surgery. Due to its stimulant effects, **USN PHEDRACUT LAVA BURN** might interfere with surgical procedures by increasing heart rate and blood pressure.

- Use with caution in patients with diabetes, as **USN PHEDRACUT LAVA BURN** can influence blood sugar levels in these patients; monitor closely. Dose adjustments to antidiabetic medication might be necessary.

- USN PHEDRACUT LAVA BURN** can inhibit platelet aggregation and increase the risk of bruising and bleeding in patients with bleeding disorders. Use with caution.

- Use with caution in patients with hypothyroidism. L-carnitine can decrease the effectiveness of thyroid hormone replacement therapy and make symptoms of hypothyroidism worse.

- Use with caution if you previously had a seizure. L-carnitine might make seizures more likely in people who have had seizures before.

- Use with caution in patients with a history of peptic ulcer disease and avoid in patients with an active peptic ulcer.

- Use with caution in patients with anxiety disorders. The caffeine might aggravate anxiety disorders.

- Do not exceed the daily recommended dose.

- Not recommended for use in persons under the age of 18 years.

INTERACTIONS:

- Anticoagulant/Antiplatelet medicine:** **USN PHEDRACUT LAVA BURN** can inhibit platelet aggregation and therefore might increase the risk of bleeding when used concomitantly with anticoagulant or antiplatelet medicine, including aspirin, clopidogrel, heparin, indomethacin and warfarin.

- QT-prolonging medicine:** **USN PHEDRACUT LAVA BURN** could have an additive effect when combined with medicines that prolong the QT interval and potentially increase the risk of ventricular arrhythmia. Medicines that prolong the QT interval include amiodarone, quinidine, sotalol, and others.

- Antidiabetic medicine:** Concomitant use of **USN PHEDRACUT LAVA BURN** and antidiabetic medicine might interfere with blood glucose control and increase the risk of hypoglycemia. Consult your doctor before using. Antidiabetic medicine includes glimepiride, insulin, metformin, and others.

- Ephedrine and other stimulants:** The use of **USN PHEDRACUT LAVA BURN** with ephedrine can increase the risk of stimulatory adverse effects. Using ephedrine with caffeine might increase the risk of serious life-threatening or debilitating adverse effects such as hypertension, myocardial infarction, stroke, seizures, and death. Avoid taking **USN PHEDRACUT LAVA BURN** with ephedrine, pseudoephedrine, phenylpropanolamine, and other stimulants.

- Monoamine Oxidase Inhibitors (MAOIs):** Concurrent use of MAOIs with caffeine might increase blood pressure raising effects and potentially cause a hypertensive crisis. Avoid using **USN PHEDRACUT LAVA BURN** with MAOIs. MAOIs include phenelzine, tranlycypromine and others.

- Thyroid hormone replacements:** L-carnitine may stop thyroid hormone from getting into cells, and may make thyroid hormone replacement less effective. If you take thyroid hormone replacements, e.g. thyroxine or levothyroxine, consult your healthcare practitioner before taking **USN PHEDRACUT LAVA BURN**.

- Hepatotoxic medicine:** *Garcinia* can elevate liver enzymes. Concomitant use with other potentially hepatotoxic medicine might increase the risk of developing liver damage. Some medicines that can adversely affect the liver include paracetamol (acetaminophen), amiodarone, carbamazepine, isoniazid, methotrexate, methyl dopa, and others.

- Herbs and supplements with stimulant properties:** Bitter orange supplements as well as other caffeine-containing supplements such as coffee, guarana, and maté seem to increase the risk of hypertension and adverse cardiovascular effects when used with **USN PHEDRACUT LAVA BURN**.

- Panax Ginseng:** Panax ginseng might prolong the QT interval. Combining with caffeine can have additive effects on the QT interval and increase the risk for arrhythmia.

PREGNANCY AND LACTATION:

Safety has not been established for use during pregnancy and lactation. Do not use **USN PHEDRACUT LAVA BURN** if you are pregnant or lactating.

DOSAGE AND DIRECTIONS FOR USE:

Adults: Mix 1 sachet into a 500 ml bottle of mineral water, and shake well. Take 1 – 2 times daily, preferably 30 minutes prior to meals or snacks.

It is recommended that the first dosage be taken in the morning on an empty stomach, 30 minutes prior to a morning workout or breakfast. Can also be taken as a refreshing energising drink during training. Do not use after 4 pm. Take **USN PHEDRACUT LAVA BURN** for 5 consecutive days of the week and stop use for 2 days before continuing again (2 off days).

SIDE EFFECTS:

The following side effects may be associated with the use of **USN PHEDRACUT LAVA BURN**:

- Blood disorders:** *Frequency unknown* – Increased bleeding risk.

- Immune system disorders:** *Frequency unknown* – Hypersensitivity and/or allergic reactions.

- Endocrine disorders:** *Frequency unknown* – Hypoglycaemia.

- Psychiatric disorders:** *Frequency unknown* – Anxiety disorders, irritability and mood changes.

- Nervous system disorders:** *Frequency unknown* – Dizziness, memory loss, difficulty in concentration, insomnia, paresthesia, syncope, seizure, stroke, migraine, headache.

- Eye disorders:** *Frequency unknown* – May worsen narrow-angle glaucoma.

- Cardiac disorders:** *Frequency unknown* – Hypertension, tachycardia/tachyarrhythmia, ventricular fibrillation, QT prolongation, flushing, ischemic stroke, variant angina and myocardial infarction.

- Gastrointestinal disorders:** *Frequency unknown* – Abdominal cramps, gastrointestinal upset, indigestion, nausea, diarrhoea and stomach ulcer.

- Hepato-biliary disorders:** *Frequency unknown* – Liver toxicity, jaundice.

- Skin and subcutaneous tissue disorders:** *Frequency unknown* – Skin rash, pruritus, cutaneous tingling.

- Musculoskeletal disorders:** *Frequency unknown* – Muscle weakness in uremic patients.

Should your general health worsen, or if you experience any untoward effects or allergic reactions while taking this medicine, please consult your doctor, pharmacist or other healthcare professional immediately.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

None known. If suspected overdose occurs, please consult your healthcare practitioner immediately. Treatment should be symptomatic and supportive.

IDENTIFICATION:

Pale red powder with distinctive cherry taste.

PRESENTATION:

Black plastic sachets with 5 g powder, packed inside a black USN carton containing 20 sachets.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated by the Authority.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

USN Pty (Ltd)
Building C, Southdowns Office Park, 2nd Floor,
21 Karee Street, Irene Ext 54,
0157
Tel: 0861 111 876

DATE OF PUBLICATION OF THE PACKAGE INSERT:

August 2014.

COMPLEMENTARY MEDICINE:

Discipline: Combination Product – Western Herbal Medicine & Health Supplement.

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

PHE046/072/PI-PI/B

JOB: SAHC_PhedracuLavaBurn PI/PI/L	SIZE: 250mm x 390mm
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"/> Doming <input type="checkbox"/> Embossing

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:

USN®

USN PHEDRACUT LAVA BURN

(powder)

Read all of this leaflet carefully because it contains important information for you.

USN PHEDRACUT LAVA BURN is available without a doctor's prescription. Nevertheless, you still need to use USN PHEDRACUT LAVA BURN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **USN PHEDRACUT LAVA BURN** with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT USN PHEDRACUT LAVA BURN CONTAINS:

Active ingredients:		
Each sachet (5 g) contains:		%NRV*
<i>Garcinia cambogia</i> extract (60 % HCA)	830 mg	
N-Acetyl-L-Carnitine	500 mg	
Total Caffeine (from Caffeine Anhydrous & Green Coffee Bean extract)	300 mg	
Calcium-HMB (Hydroxy Methyl Butyrate)	250 mg	3 %
Fucoxanthin extract (10 %)	240 mg	
Green Coffee Bean (<i>Coffea robusta</i>) extract (45 % Chlorogenic Acid)	200 mg	
Phosphatidylserine (20 %)	150 mg	
N-Acetyl-L-Glutamine	100 mg	
Vitamin B ₃ (as Nicotinic Acid)	17 mg	106 %
Chromium (as Chromium Picolinate)	25 µg	71 %

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

Inactive ingredients: Coloursants, Flavourings, Fructooligosaccharide (FOS), Malic acid, Non-nutritive sweeteners (Sucralose & Acesulfame-K).

Sugar Free

Contains Sweeteners (Sucralose 200 mg & Acesulfame-K 20 mg per 5 g)

2. WHAT USN PHEDRACUT LAVA BURN IS USED FOR:

USN PHEDRACUT LAVA BURN is indicated as an aid to a weight management programme that includes an energy-restricted diet and regular exercise, as a thermogenic agent.

3. BEFORE YOU TAKE USN PHEDRACUT LAVA BURN:

Do not take USN PHEDRACUT LAVA BURN:

- If you are hypersensitive (allergic) to any of the active or inactive ingredients (see **WHAT USN PHEDRACUT LAVA BURN CONTAINS**).
- If you are pregnant or breastfeeding your baby (see **Pregnancy and Breastfeeding**).
- If you have a liver disease. **USN PHEDRACUT LAVA BURN** might worsen liver damage.
- If you have any renal dysfunction. Chromium might worsen renal disease.
- If you are under 18 years of age.

Take special care with USN PHEDRACUT LAVA BURN:

- If you have high blood pressure. Caffeine can increase blood pressure.
- If you suffer from long QT syndrome. Caffeine might prolong the QT interval in some patients and increase the risk of ventricular arrhythmia (abnormally rapid heart rhythms originating in the ventricles of the heart).
- USN PHEDRACUT LAVA BURN** can increase the heart rate due to the caffeine content. It can cause tachyarrhythmia (increased heart rate) in healthy individuals and might worsen symptoms in patients already suffering from tachyarrhythmia.
- If you are having elective surgery within two weeks. The stimulant effects of **USN PHEDRACUT LAVA BURN** might interfere with surgical procedures by increasing the heart rate and blood pressure.
- If you have diabetes. **USN PHEDRACUT LAVA BURN** can influence blood sugar levels. Dose adjustments to antidiabetic medicine might be necessary. Monitor closely.
- If you have a bleeding disorder. **USN PHEDRACUT LAVA BURN** can inhibit platelet aggregation and increase the risk of bruising and bleeding. Use with caution.
- If you have an underactive thyroid. L-carnitine can make thyroid hormone replacement therapy less effective and make symptoms of an underactive thyroid worse.
- If you previously had a seizure (fit). L-carnitine can increase your chances of a seizure (fit) if you previously had one.
- If you have a history of a stomach ulcer or an active stomach ulcer – avoid.
- If you have an anxiety disorder, the caffeine might worsen the symptoms.
- Do not exceed the daily recommended dose.

Taking USN PHEDRACUT LAVA BURN with food and drink:

- USN PHEDRACUT LAVA BURN** should preferably be taken 30 minutes prior to meals or snacks.

Pregnancy and Breastfeeding:

- Safety has not been established for use during pregnancy and breastfeeding. Avoid use.

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS:

Nie geskeduleer nie.

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:

USN®

USN PHEDRACUT LAVA BURN

(poeier)

Lees die hele pamflet noukeurig deur, aangesien dit belangrike inligting vir u bevat.

USN PHEDRACUT LAVA BURN is beskikbaar sonder 'n dokter se voorskrif. Nietemin moet u steeds **USN PHEDRACUT LAVA BURN** versigtig gebruik om die beste resultate te verkry.

- Bewaar hierdie pamflet. U mag dit dalk weer moe lees.
- Moenie **USN PHEDRACUT LAVA BURN** met enige ander persoon deel nie.
- Vra u apteker indien u verdere inligting of advies benodig.

1. WAT USN PHEDRACUT LAVA BURN BEVAT:

Aktiewe bestanddele:		
Elke sakkie (5 g) bevat:		%NRV*
<i>Garcinia Cambogia</i> ekstrakt (60 % HCA)	830 mg	
N-Aseties-L-Karnities	500 mg	
Totale Kafeïen (van Anhidriese Kafeïen & Groenkoffieboon-ekstrakt)	300 mg	
Kalsium-HMB (Hidroksie-metielbutyraat)	250 mg	3 %
Fukoxantien ekstrakt (10 %)	240 mg	
Groenkoffieboon (<i>Coffea robusta</i>) ekstrakt (45 % Chlorogeensuur)	200 mg	
Fosfatidiesierien (20 %)	150 mg	
N-Aseties-L-Glutamien	100 mg	
Vitamiën B ₃ (as Nikotiensuur)	17 mg	106 %
Chroom (as Chroompikolinaat)	25 µg	71 %

*%Nutriëntverwysingswaardes (NwVs) vir individue 4 jaar en ouer (2010)

Onaktiewe bestanddele: Appelsuur, Fruito-oligosakkariede (FOS), Geurmiddels, Kleurmiddels, Kunsmatige versoeters (Sukralose & Acesulfaam-K).

Suikevrny

Bevat Versoeters (Sukralose 200 mg & Acesulfaam-K 20 mg per 5 g)

2. WAARVOOR USN PHEDRACUT LAVA BURN GEBRUIK WORD:

USN PHEDRACUT LAVA BURN word aangedui as 'n hulpmiddel in 'n gewigsbeheerprogram wat 'n energiebeperkte dieet en gereelde oefening insluit, as 'n termogeniese middel.

3. VOOR U USN PHEDRACUT LAVA BURN NEEM:

Moenie USN PHEDRACUT LAVA BURN neem:

- Indien u hipersensitief (allergies) is vir enige van die aktiewe of onaktiewe bestanddele (sien **WAT USN PHEDRACUT LAVA BURN BEVAT**).
- Indien u swanger is of u baba borsvoed (sien **Swangerskap en Borsvoeding**).
- Indien u 'n lewersiekte het. **USN PHEDRACUT LAVA BURN** kan lewerskade vererger.
- Indien u enige nierdiersfunksie het. Chroom kan niersiektes vererger.
- Indien u jonger as 18 jaar is.

Neem spesiale sorg met USN PHEDRACUT LAVA BURN:

- Indien u aan hoë bloeddruk ly. Kafeïen kan bloeddruk verhoog.
- Indien u aan lang-QT-sindroom ly. Kafeïen kan die QT-interval in sommige pasiënte verleng en die risiko van ventrikulêre arritmie (abnormaal winsige prosedures deur hartklop en die ventrikels van die hart) verhoog.
- USN PHEDRACUT LAVA BURN** kan hartklop verhoog as gevolg van die kafeïen inhoud. Dit kan tagi-arritmie (verhoogde hartklop) in gesonde individue veroorsaak en mag simptome vererger in pasiënte wat reeds ly aan tagi-arritmie.
- Indien u binne die volgende twee weke elektiewe chirurgie ondergaan. Die stimulerende effek van **USN PHEDRACUT LAVA BURN** mag inmeng met chirurgiese prosedures deur hartklop en bloeddruk te verhoog.
- Indien u 'n diabeet is, kan **USN PHEDRACUT LAVA BURN** bloedsuikervlakke beïnvloed. Dosisaanpassings ten opsigte van antidiabetiese medisyne mag nodig wees. Monitor noukeurig.
- Indien u aan 'n bloedingsiekte ly, mag **USN PHEDRACUT LAVA BURN** die sameklompng van bloedplaatjies inhibeer en die risiko van kneusing en bloeding verhoog. Gebruik met omsigtigheid.
- Indien u 'n onderaktiewe skildklier het. L-karnities kan tiroïedhormoonvervangings terapie minder effektiëf maak en simptome van 'n onderaktiewe skildklier vererger.
- Indien u voorheen konvulsies gehad het. L-karnities kan u kanse van konvulsies verhoog as u voorheen konvulsies gehad het.
- Vermyn indien u 'n geskiedenis van maagsere of 'n aktiewe maagseer het.
- Indien u aan 'n ansversteuring ly, mag die kafeïen die simptome vererger.
- Moenie die voorgeskrewe daaglikse dosis oorskry nie.

Neem van USN PHEDRACUT LAVA BURN met voedsel en drank:

- USN PHEDRACUT LAVA BURN** moet verkieslik 30 minute voor etes of versnaperings geneem word.

Swangerskap en Borsvoeding:

- Die veiligheid van die gebruik van hierdie produk tydens swangerskap en borsvoeding is nie vasgestel nie. Vermyn gebruik.

Driving and using machinery:

It is unlikely that **USN PHEDRACUT LAVA BURN** will affect your ability to drive a vehicle or operate machinery requiring your attention.

Taking other medicines with USN PHEDRACUT LAVA BURN:

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

If you are on any of the following medicine or treatment, you should discuss the use of **USN PHEDRACUT LAVA BURN** with your doctor or pharmacist first:

- Anticoagulant/Antiplatelet medicine (such as aspirin, clopidogrel, heparin, indomethacin and warfarin), as **USN PHEDRACUT LAVA BURN** can inhibit platelet aggregation and might increase the risk of bleeding when used with these medicines.
- QT-prolonging medicine (such as amiodarone, quinidine, sotalol, etc.), as **USN PHEDRACUT LAVA BURN** could have an additive effect when combined with these medicines and increase the risk of ventricular arrhythmia (abnormally rapid heart rhythms originating in the ventricles of the heart).
- Antidiabetic medicine (such as glimepiride, insulin, metformin, etc.). Use of these medicines with **USN PHEDRACUT LAVA BURN** might interfere with blood glucose control and increase the risk of low blood sugar.
- Ephedrine and other stimulants (such as pseudoephedrine, phenylpropanolamine, etc.). These stimulants can increase the risk of stimulatory adverse effects when used with **USN PHEDRACUT LAVA BURN**. The use of ephedrine with caffeine might increase the risk of serious life-threatening adverse effects such as high blood pressure, heart attack, stroke, fits and death. Avoid using together.
- Monoamine Oxidase Inhibitors (MAOIs) (such as phenelzine, tranylcypromine and others), as these medicines used with caffeine might increase blood pressure and could cause a hypertensive crisis. Avoid using together.
- Thyroid hormone replacements (such as thyroxine and levothyroxine), as L-carnitine might make these medicines less effective.
- Hepatotoxic medicine (such as paracetamol, amiodarone, carbamazepine, isoniazid, methotrexate, methyldopa, etc.), as *garcinia cambogia* in **USN PHEDRACUT LAVA BURN** can elevate liver enzymes and concomitant use might increase the risk of developing liver damage.
- Herbs and supplements with stimulant properties (bitter orange supplements as well as other caffeine-containing herbs and supplements such as coffee, guarana, maté, etc.), can increase the risk of high blood pressure and adverse heart effects when used with **USN PHEDRACUT LAVA BURN**.
- Panax ginseng, as it might prolong the QT interval when combined with caffeine in **USN PHEDRACUT LAVA BURN** and can increase the risk for arrhythmia (irregular heart rate).

4. HOW TO TAKE USN PHEDRACUT LAVA BURN:

Do not share medicines prescribed for you with any other person. Always take **USN PHEDRACUT LAVA BURN** exactly as directed. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

- Adults:* Mix 1 sachet into a 500 ml bottle of mineral water, and shake well. Take 1 – 2 times daily, preferably 30 minutes prior to meals or snacks.

It is recommended that the first dosage be taken in the morning on an empty stomach, 30 minutes prior to a morning workout or breakfast. Can also be taken as a refreshing energising drink during training. Do not use after 4 pm. Take **USN PHEDRACUT LAVA BURN** for 5 consecutive days of the week and stop use for 2 days before continuing again (2 off days).

If you take more USN PHEDRACUT LAVA BURN than you should:

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take USN PHEDRACUT LAVA BURN:

Take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose but simply take your next dose at the normal time. Do not take a double dose to make up the one you missed.

5. POSSIBLE SIDE EFFECTS:

- USN PHEDRACUT LAVA BURN** can have side effects.
- Not all side effects reported for **USN PHEDRACUT LAVA BURN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.
- If any of the following happens, stop taking **USN PHEDRACUT LAVA 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 **USN PHEDRACUT LAVA BURN**. You may need urgent medical attention or hospitalisation.

- Tell your doctor immediately or go to the casualty department at your nearest hospital if any of the following happens:
 - Seizure (fit).
 - Stroke/ischemic stroke.
 - Heart attack.
 - Angina (chest pain).

These are all serious side effects. You may need urgent medical attention.

- Tell your doctor as soon as possible if you notice any of the following:
 - High blood pressure.
 - Increased/irregular heart rate.
 - Flushing*.
 - Increased bleeding.
 - Low blood sugar.
 - Increased anxiety, irritability or mood changes*.
 - Dizziness, memory loss or difficulty in concentration.
 - Insomnia (difficulty falling/staying asleep).
 - Burning/prickling sensation of the skin.
 - Migraine or headache*.
 - Abdominal cramps, gastrointestinal upset, diarrhoea or indigestion.
 - Nausea*.
 - Symptoms of a stomach ulcer.
 - Jaundice (yellowish pigmentation of the skin and whites of the eyes).
 - Muscle weakness in uremic patients.

*These side effects commonly occur with slimming agents that contain stimulants and usually subside within 2 weeks of use.

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

6. STORING AND DISPOSING OF USN PHEDRACUT LAVA BURN:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Do not store in the bathroom.
- Store in its original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the container.
- Do not use **USN PHEDRACUT LAVA BURN** if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF USN PHEDRACUT LAVA BURN:

Black plastic sachets with 5 g powder, packed inside a black USN carton containing 20 sachets.

8. IDENTIFICATION OF USN PHEDRACUT LAVA BURN:

Pale red powder with distinctive cherry taste.

9. REGISTRATION NUMBER:

To be allocated by the Authority.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

USN Pty (Ltd)
Building C, Southdowns Office Park, 2nd Floor,
21 Karee Street, Irene Ext 54,
0157
Tel: 0861 111 876

11. DATE OF PUBLICATION:

August 2014.

12. COMPLEMENTARY MEDICINE:

Discipline: Combination Product – Western Herbal Medicine & Health Supplement.

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

- Stel u dokter so gou as moontlik in kennis sou u enige van die volgende opmerk:

- Hoë bloeddruk.
- Verhoogde/ornreëmatige hartklop.
- Gloede*.
- Verhoogde bloeding.
- Lae bloedsuiker.
- Verhoogde angstigheid, irritasie of gemoedsveranderinge*.
- Duiseligheid, geheueverlies of konsentrasieprobleme.
- Slaaploosheid (suikkel om aan die slaap te raak/te bly).
- Brandende/prikkelende sensasie van die vel.
- Migraine of hoofpyn*.
- Maagkrampe, maagongesteldheid, diarree of slegte spysvertering.
- Naarheid*.
- Simptome van 'n maagseer.
- Geelstug (gelerige pigmentasie van die vel en die wit van die oë).
- Spierswakheid in uremiese pasiënte.

*Hierdie newe-effekte kom algemeen voor by verslankingsmiddels wat stimulerende bevat en verduyn gewoonlik binne 2 weke van gebruik.

- Indien u enige newe-effekte waarneem wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

6. BERGING EN WEGDOENING VAN USN PHEDRACUT LAVA BURN:

- Bewaar alle medikasie buite bereik van kinders.
- Bewaar teen of benede 25 °C.
- Beskerm teen lig en vog.
- Moenie die produk in die badkamer bewaar nie.
- Bewaar in die oorspronklike houër.
- Hou die houër dig toe.
- Moenie gebruik na die vervaldatum aangedui op die houër nie.
- Moenie **USN PHEDRACUT LAVA BURN** gebruik indien u enige sigbare tekens van produkafbraek opmerk nie.

Neem alle ongebruikte medikasie terug na u apteker.

Moenie ongebruikte medikasie in dreine of rioolstelsels (bv. toilette) afspoel nie.

7. AANBIEDING VAN USN PHEDRACUT LAVA BURN:

Swart plastieksakkies met 5 g poeier, verpak in 'n swart USN-karton met 20 sakkies.

8. IDENTIFIKASIE VAN USN PHEDRACUT LAVA BURN:

Ligte rooi poeier met kenmerkende kersleuger.

9. REGISTRASIENOMMER:

Vir toekenning deur die Raad.

10. NAAM EN ADRES VAN REGISTRASIEHOUER:

USN (Edms) Bpk
Gebou C, Southdowns Besigheidspark, 2de Vloer,
Kareestraat 21, Irene Uitbr. 54,
0157
Tel: 0861 111 876

11. DATUM VAN PUBLIKASIE:

Augustus 2014.

12. KOMPLEMENTÊRE MEDISYNE:

Dissipline: Kombinasie Produk – Westerse Kruiemedikasie & Gesondheidsaanwilling.

Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy kwaliteit, veiligheid of beoogde gebruik nie.

JOB: SAHC_PhedracutLavaBurn PI/PIL	SIZE: 250mm x 390mm
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"/> Doming <input type="checkbox"/> Embossing