

PROFESSIONAL INFORMATION

SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:



USN PHEDRACUT LIPO X GOLD

36856 P13

(capsules)

COMPOSITION:

ACTIVE INGREDIENTS:	Per Capsule	Per Dose	%NRV
Reduxoslim™ blend <i>Sphaeranthus indicus</i> L. [flower head; 4:1 extract]	150 mg	300 mg	
<i>Garcinia mangostana</i> L. [fruit rind; 4:1 extract]	50 mg	100 mg	
Caffeine Anhydrous	100 mg	200 mg	
L-Theanine	50 mg	100 mg	
Max-NR-Gex™ [<i>Alpinia officinarum</i> Hance (Galangal) (root; 10:1 extract)]	37,5 mg	75 mg	
Thermozine™ [<i>Aframomum melegueta</i> (Grains of Paradise) (seed; 10:1 extract)]	20 mg	40 mg	
Chromium picolinate providing Chromium (elemental)	417 µg 50 µg	834 µg 100 µg	286 %

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

Other ingredients: Bovine gelatine capsules, colloidal silicon dioxide (Aerosil®), magnesium stearate, potato starch.

Sugar Free

CATEGORY AND CLASS:

D 33.7 Combination Product

PHARMACOLOGICAL ACTION:

Reduxoslim™ blend - *Sphaeranthus indicus* (flower head) & *Garcinia mangostana* (fruit rind) extract: A blend composing extracts of the flower heads from *Sphaeranthus indicus* and the fruit rinds of *Garcinia mangostana* blended together in a ratio of 3:1 was shown to be effective in inhibiting adipogenesis while promoting lipolysis.

Caffeine Anhydrous: 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 non-oxidative 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.

L-Theanine: L-Theanine's anxiolytic effects might be due to its effects on glutamate receptors and the possibility that it increases inhibitory neurotransmitters such as glycine or gamma-aminobutyric acid (GABA). Theanine's improvement in certain components of cognitive function may be secondary to its effects on alpha-wave activity. Theta waves also indicate cognitive alertness. Research also suggests theanine may act synergistically with caffeine to assist with weight loss.

Max-NR-Gex™ - *Alpinia officinarum* Hance (Galangal) extract: *Alpinia officinarum*, a plant species of the *Zingiberaceae* family, contains high concentrations of the flavonol, galangin. Historically, the rhizomes were reputed to have stimulant and digestive effects. Galangin in *Alpinia officinarum*, demonstrated antioxidative and free radical scavenging activities capable of modulating enzyme activities and suppressing the genotoxicity of chemicals. The galangal, the rhizome of *Alpinia officinarum* Hance, can also inhibit fatty-acid synthase.

Thermozine™ - *Aframomum melegueta* (Grains of Paradise) extract: Grains of Paradise, a species of the ginger family, contain pungent, aromatic ketones such as 6-paradol, 6-gingerol and 6-shogaol. An alcohol extract of Grains of Paradise seeds and 6-paradol are known to activate brown adipose tissue (BAT) thermogenesis. Grains of Paradise has been found to help convert White Adipose Tissue (WAT) into Brown Adipose Tissue (BAT), therefore converting the energy storing fat tissue into the fat tissue that helps increase thermogenesis and total calorie expenditure.

Chromium (from Chromium Picolinate): 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. Therefore, taking chromium before a high carbohydrate meal seems to lessen postprandial hyperglycaemia. Chromium picolinate may also reduce fat cravings and hunger by affecting the brain's hunger receptor. This is due to the fact that chromium might sensitise insulin-sensitive glucoreceptors in the brain, resulting in appetite suppression, stimulation of thermogenesis and down-regulation of insulin secretion.

INDICATIONS:

USN PHEDRACUT LIPO X GOLD is indicated as a thermogenic agent that provides added energy as an aid to a weight management programme combined with a balanced, energy-restricted diet and regular exercise.

CONTRAINDICATIONS:

This product is contraindicated for individuals that are hypersensitive (allergic) to any of the listed ingredients. This includes an allergy to ginger, as *Aframomum melegueta* (Grains of Paradise) is a member of the *Zingiberaceae* (ginger) family.

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

Do not use if you are pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS:

- Use with caution in patients with hypertension. Caffeine can temporarily increase blood pressure.
- Use with caution in patients with cardiac conditions. Caffeine, especially taken in high doses, can induce cardiac arrhythmias in individuals sensitive to caffeine.
- Discontinue at least two weeks before elective surgery. Due to its stimulant effects, **USN PHEDRACUT LIPO X GOLD** might interfere with surgical procedures by increasing heart rate and blood pressure.
- Use with caution in patients with diabetes. **USN PHEDRACUT LIPO X GOLD** can influence blood sugar levels in diabetic patients; monitor closely. Dose adjustments to antidiabetic medication might be necessary.
- USN PHEDRACUT LIPO X GOLD** 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 anxiety disorders: the caffeine might aggravate the symptoms.
- Use with caution in patients with liver disease; **USN PHEDRACUT LIPO X GOLD** might exacerbate liver dysfunction.
- Epileptic patients should use with caution. Caffeine can increase the risk for seizures and can decrease the activity of some anticonvulsant medicines.
- USN PHEDRACUT LIPO X GOLD** might temporarily increase intraocular pressure in patients with narrow-angle glaucoma due to the caffeine content; glaucoma patients should use with caution.
- Use with caution in patients with renal disease; **USN PHEDRACUT LIPO X GOLD** might exacerbate renal dysfunction.
- Use with caution in patients with a stomach ulcer as *Alpinia officinarum* Hance (Galangal) extract in **USN PHEDRACUT LIPO X GOLD** can increase stomach acid and worsen the condition.
- Do not exceed the daily recommended dose.

INTERACTIONS:

- Anticoagulant/antiplatelet medicine:** **USN PHEDRACUT LIPO X GOLD** 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.
- Anticonvulsant medicine:** **USN PHEDRACUT LIPO X GOLD** could lower the effect of anticonvulsant medicine due to its caffeine content. Taking caffeine in combination with one of the following medicines could reduce the effect of the medicine and increase the risk of seizures: Carbamazepine, ethosuximide, felbamate, phenytoin and valproate.
- Antidiabetic medicine:** Concomitant use of **USN PHEDRACUT LIPO X GOLD** and antidiabetic medicine might interfere with blood glucose control and increase the risk of hypoglycaemia. Consult your doctor before using. Antidiabetic medicine includes glimepiride, insulin, metformin, and others.
- Ephedrine and other stimulants:** The use of **USN PHEDRACUT LIPO X GOLD** 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 LIPO X GOLD** 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 LIPO X GOLD** with MAOIs. MAOIs include phenelzine, tranylcypromine and others.
- Levothyroxine:** The use of **USN PHEDRACUT LIPO X GOLD** with levothyroxine might decrease serum levels of levothyroxine due to chromium that can bind levothyroxine in the intestinal tract and decrease absorption. Take levothyroxine at least 30 minutes before or 3-4 hours after taking **USN PHEDRACUT LIPO X GOLD**.
- Antacids:** *Alpinia officinarum* Hance (Galangal) extract in **USN PHEDRACUT LIPO X GOLD** can increase stomach acid. By increasing stomach acid, *Alpinia officinarum* might decrease the effectiveness of antacids. Antacids include calcium carbonate, dihydroxyaluminium sodium carbonate, aluminium hydroxide, and others.
- H2-blockers and proton pump inhibitors (PPIs):** *Alpinia officinarum* Hance (Galangal) extract in **USN PHEDRACUT LIPO X GOLD** may increase stomach acid. By increasing stomach acid, *Alpinia officinarum* might decrease the effectiveness of medications that decrease stomach acid, called H2-blockers and proton pump inhibitors (PPIs). H2-blockers include cimetidine, ranitidine, etc. and proton pump inhibitors include omeprazole, lansoprazole, pantoprazole and esomeprazole.
- Herbs and supplements with stimulant properties:** Bitter orange supplements as well as other caffeine-containing herbs and supplements such as coffee, guarana and maté can increase the risk of hypertension and cardiovascular adverse effects when used with **USN PHEDRACUT LIPO X GOLD**.
- Herbs and supplements with anticoagulant/antiplatelet properties:** Herbs that affect platelet aggregation such as garlic, ginger, turmeric and others, can increase the risk of bruising and bleeding when used with **USN PHEDRACUT LIPO X GOLD**.
- Herbs and supplements with hypoglycaemic potential:** Herbs and supplements with hypoglycaemic potential (such as fenugreek, garlic, Panax ginseng and others) can have additive blood glucose lowering effects when used with **USN PHEDRACUT LIPO X GOLD**.

HUMAN REPRODUCTION:

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

DOSAGE AND DIRECTIONS FOR USE:

Adults: Take 2 capsules twice daily on an empty stomach with a glass of water (at least 30 minutes prior to a meal, snack or workout).

Start with 1 capsule to assess tolerance and increase dosage to a maximum of 2 capsules (full dosage) as tolerated (maximum 4 capsules per day).

Take **USN PHEDRACUT LIPO X GOLD** for 5 consecutive days of the week and stop use for 2 days before continuing again. **USN PHEDRACUT LIPO X NIGHT** can be used during off-cycle and before evening meals. **USN PHEDRACUT LIPO X GOLD** is not recommended after 4 pm.

Do not exceed the recommended daily dosage.

SIDE EFFECTS:

The following side effects may be associated with the use of **USN PHEDRACUT LIPO X GOLD**:

- 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, agitation, mood changes.
- Nervous system disorders:** *Frequency unknown* – Dizziness, insomnia, headache, nervousness, restlessness.
- Eye disorders:** *Frequency unknown* – Increased intraocular pressure in patients with narrow-angle glaucoma.
- Cardiac disorders:** *Frequency unknown* – Elevated blood pressure, tachycardia/tachyarrhythmia.
- Gastrointestinal disorders:** *Frequency unknown* – Abdominal cramps, gastric irritation, abdominal bloating, flatulence, constipation, dyspepsia, reflux, heartburn, nausea, vomiting, diarrhoea, decreased appetite.
- Hepato-biliary disorders:** *Frequency unknown* – Hepatotoxicity.
- Skin and subcutaneous tissue disorders:** *Frequency unknown* – Urticaria.
- Musculoskeletal disorders:** *Frequency unknown* – Muscular tremors.
- Renal and urinary disorders:** *Frequency unknown* – Diuresis, renal disease.

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:

Pearl white gelatine capsules containing light brown powder with white and dark speckles.

PRESENTATION:

White HDPE plastic container with a white USN lid, containing 80 capsules, packed inside a carton.

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)
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21 Karee Street, Irene Ext 54
0157
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

September 2019.

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.

JOB: SACE_PhedraCut Lipo X Gold_PI/PIL	SIZE: 300mm x 385mm
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/>	
COLOURS: <input type="checkbox"/> K	FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Blurring <input type="checkbox"/> Embossing

