

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:



USN PHEDRACUT LIPO X NIGHT

(capsules)

COMPOSITION:

Active ingredients:

	Per Capsule	Per Dose	*%NRV (per dose)
Acetyl-L-Carnitine HCl	250 mg	500 mg	
GarCitrin® (standardised <i>Garcinia cambogia</i> extract – 50 % HCA, 5 % Garcinol)	125 mg	250 mg	
<i>Gymnema sylvestre</i> Leaf Powder	100 mg	200 mg	
Paradoxine® Grains of Paradise (<i>Aframomum melegueta</i>) seed extract (12.5 % 6-Paradol)	20 mg	40 mg	
BioPerine® (Black Pepper) (<i>Piper nigrum</i> L.) extract (standardised to 95 % Piperine)	2.5 mg	5 mg	
Chromium (from Chromium Piccolinate)	50 µg	100 µg	286 %

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

Other ingredients: Bovine gelatine capsules, magnesium stearate, maize starch, silicon dioxide.

Sugar Free

CATEGORY AND CLASS:

D 33.7 Combination Product

PHARMACOLOGICAL ACTION:

Acetyl-L-Carnitine HCl: 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.

GarCitrin®: Garcitrin® (Garcinol 5%) is a standardised extract obtained from *Garcinia cambogia* and contains a minimum of 50 % (-) Hydroxycitric acid (HCA) and 5 % Garcinol. Garcinol enhances the biological action of HCA. HCA has been shown to inhibit citrate cleavage enzyme, suppress de *ново* fatty acid synthesis and food intake, and decrease body weight gain. It competitively inhibits the extra mitochondrial enzyme adenosine triphosphate-citrate (pro-3S)-lyase which catalyses the conversion of citrate and coenzyme A to oxaloacetate and acetyl coenzyme A (acetyl- CoA), the primary building blocks of fatty acid and cholesterol synthesis. As a citrate cleavage enzyme it may play a role in de *ново* lipogenesis inhibition. HCA's efficacy in inhibiting ATP citrate-lyase depends entirely on the presence of HCA inside the target cell, and reduced HCA absorption would decrease its weight-lowering effects.

***Gymnema sylvestre* Leaf Powder:** The major biologically active molecules in *Gymnema sylvestre* leaves are called gymnemic acids, a class of triterpenoid saponins. The mode of action is through stimulation in insulin secretion from the pancreas. It also exerts a similar effect by delaying the glucose absorption in the blood. The atomic arrangements of gymnemic acids to the taste buds are similar to sugar molecules which fill the receptors in the taste buds preventing its activation by the sugar molecule in the food. Similarly, in the intestine it attaches to the receptor present in external layer of intestine, thereby preventing the absorption of sugar molecules by intestine, leading to reduction in blood sugar levels. Gurmarin acts in a similar manner by interfering with the ability of taste buds on the tongue to differentiate between sweet and bitter. Hypoglycaemic effect of gymnemic acids includes a cascade of events starting from modulation of incretin activity which triggers insulin secretion and release. It also increases regeneration of pancreatic islet cells to enhanced enzyme mediated uptake of glucose. This process decreased glucose and fatty acid assimilation in the small intestine and interferes in the ability of receptors in mouth and intestine to sensation of sweetness. It has been previously reported in the literature that the action of gymnemic acid is similar to that of incretin-mimetic mechanism of action. Gymnemic acid has been found to interact with glyceraldehyde-3-phosphate dehydrogenase (GAPDH), a key enzyme in glycolysis pathway. The findings also indicated that the acyl moieties present in gymnemic acids play an important role for the GA-induced smearing of GAPDH and G3PDH and play an integral role in the antihyperglycemic activity of GA derivatives.

Paradoxine® (Grains of Paradise) extract: Paradoxine® is a standardised extract of the Grains of Paradise seeds of the *Aframomum melegueta* plant. The Paradoxine® extract is standardised to contain a minimum of 15 % Aframolins and, in particular, 12,5 % 6-Paradol.

Paradoxine® 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.

BioPerine® (Black Pepper) extract: 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 utilization of the natural actives increasing the bioavailability of supplemented nutrients through increased absorption. As a thermotriener BioPerine® would potentially improve the process of nutrient absorption by enhancing thermogenesis. Most of the food or thermotriener-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, have 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 (from Chromium Piccolinate): 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 piccolinate 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 NIGHT is indicated as a stimulant-free 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.

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

Do not use if you have an existing liver disease.

Do not use if you are pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS:

- Discontinue at least two weeks before elective surgery. **USN PHEDRACUT LIPO X NIGHT** might affect blood glucose levels and interfere with blood glucose control during and after surgical procedures.
- Use with caution in patients with diabetes. **USN PHEDRACUT LIPO X NIGHT** can influence blood sugar levels in diabetic patients; monitor closely. Dose adjustments to antidiabetic medication might be necessary.
- **USN PHEDRACUT LIPO X NIGHT** 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 and chromium 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 liver disease; **USN PHEDRACUT LIPO X NIGHT** might exacerbate liver dysfunction.
- Use with caution in patients with renal disease; **USN PHEDRACUT LIPO X NIGHT** might exacerbate renal dysfunction.
- Do not exceed the daily recommended dose.

INTERACTIONS:

- **Anticoagulant/antiplatelet medicine:** **USN PHEDRACUT LIPO X NIGHT** 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.
- **Antidiabetic medicine:** Concomitant use of **USN PHEDRACUT LIPO X NIGHT** 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.
- **Levothyroxine:** The use of **USN PHEDRACUT LIPO X NIGHT** with levothyroxine might decrease serum levels of levothyroxine due to chromium and L-carnitine 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 NIGHT**.
- **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, methylodopa, and others.
- **Antidepressants:** Combining *Garcinia* with antidepressants or other serotonergic medicines might increase the risk of serotonergic side effects.
- **Tolbutamide:** *Gymnema* in **USN PHEDRACUT LIPO X NIGHT** might increase the clearance and decrease the effects of tolbutamide.
- **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 NIGHT**.
- **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 NIGHT**.

HUMAN REPRODUCTION:

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

DOSAGE AND DIRECTIONS FOR USE:

Adults: As a dietary supplement, take 2 capsules twice daily. For best results, take 30-60 minutes before exercise and the second dose before dinner. Suitable for use after 4 pm. Take a 5 day break after 6 weeks of use.

If using **PHEDRACUT LIPO X GOLD:** Take 2 capsules **PHEDRACUT LIPO X NIGHT** 30 minutes before dinner. Also take 2 capsules twice daily when taking a break from **PHEDRACUT LIPO X GOLD** (e.g. on weekends).

Do not exceed the recommended daily dosage.

SIDE EFFECTS:

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

- **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* – Mood changes.
- **Nervous system disorders:** *Frequency unknown* – Dizziness, insomnia, headache.
- **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.
- **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:

White gelatine capsules containing off-white to light brown powder.

PRESENTATION:

White HDPE plastic container with a white USN lid, containing 60 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)
Building C, Southdowns Office Park, 2nd Floor,
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October 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 Night	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"/> Other: <input type="checkbox"/>	
COLOURS:  K	FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dornring <input type="checkbox"/> Embossing

