

PROFESSIONAL INFORMATION



USN PHEDRACUT LIPO XT

37405726

(capsules)

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT)

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

USN PHEDRACUT LIPO XT capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS

	Per Capsule	Per Dose	*%NRV
<i>Garcinia cambogia</i> [fruit; 6:1 extract providing 60 % hydroxycitric acid (HCA)]	250 mg	500 mg	
Total Caffeine [from Caffeine anhydrous, Green Coffee Bean and Green Tea extract]	105 mg	210 mg	
<i>Coffea robusta</i> L. Linden (Green Coffee Bean) [seed; extract standardised to 45 % Chlorogenic Acid and 5 % Caffeine]	100 mg	200 mg	
<i>Camellia sinensis</i> L. (Kuntze) (Green Tea) [leaf; extract standardised to 40 % EGCG, 70 % Catechins, 95 % Polyphenol and 5 % Caffeine]	75 mg	150 mg	
Theacrine 99 %	25 mg	50 mg	
Zinc Lactate 3-Hydrate providing Zinc (elemental)	3,87 mg 0,85 mg	7,74 mg 1,7 mg	15 %
BioPerine® <i>Piper nigrum</i> L. (Black Pepper) [fruit; 50:1 extract standardised to 95 % Piperine]	2,5 mg	5 mg	
Calcium-D-Pantothenate providing Pantothenic acid (Vitamin B ₅)	1,30 mg 0,4 mg	2,61 mg 0,8 mg	16 %
Pyridoxine HCl providing Pyridoxine (Vitamin B ₆)	0,27 mg 0,15 mg	0,55 mg 0,30 mg	18 %

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

Sugar free.

CONTAINS CAFFEINE (105 mg per capsule).

A cup of instant coffee contains approximately 80 mg of caffeine.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Size 0 red and white hard gelatine capsules containing a light brown powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

USN PHEDRACUT LIPO XT is indicated as a thermogenic aid to assist weight loss as part of a weight management programme. Only effective when combined with a balanced, energy-restricted eating plan and regular physical activity.

4.2 Posology and method of administration

Adults:

- Take 2 capsules twice daily, 30 minutes prior to meals/snacks (preferably before breakfast and lunch). If training early morning, take 2 capsules prior to workout, and then follow with breakfast directly after training.
- USN PHEDRACUT LIPO XT is not recommended after 4 pm.
- Take USN PHEDRACUT LIPO XT for 5 consecutive days of the week and stop use for 2 days before continuing again.
- Do not exceed the recommended daily dosage.
- Consult a healthcare provider for use beyond 12 weeks.

Children:

Not suitable for children under the age of 18 years.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 2 or 6.1.

4.4 Special warnings and precautions for use

Bleeding disorders:

USN PHEDRACUT LIPO XT may have antiplatelet effects and may increase the risk of bruising and bleeding when used in patients with bleeding disorders. Patients should be advised to discontinue USN PHEDRACUT LIPO XT at least 2 weeks prior to surgical procedures (see section 4.5).

Cardiac conditions:

USN PHEDRACUT LIPO XT may reduce blood flow to the heart muscle during exercise which might lead to cardiovascular complications such as chest pain and dysrhythmia, even in healthy individuals. USN PHEDRACUT LIPO XT may also temporarily increase blood pressure when used short-term.

Diabetes mellitus:

USN PHEDRACUT LIPO XT may increase insulin levels and/or decrease blood glucose levels and cause hypoglycaemia. Dose adjustment of antidiabetic medicine might be necessary (see section 4.5).

Glaucoma:

USN PHEDRACUT LIPO XT may temporarily increase intraocular pressure in patients with narrow-angle glaucoma.

Liver disorder:

USN PHEDRACUT LIPO XT may exacerbate liver dysfunction in patients with a liver disorder. Patients should be advised to stop taking USN PHEDRACUT LIPO XT and consult a healthcare provider if they develop symptoms of liver trouble such as yellowing of the skin or eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.

Renal disease:

USN PHEDRACUT LIPO XT may exacerbate renal dysfunction in patients with renal disease. Patients with detrusor instability (overactive bladder syndrome) should consult a healthcare provider prior to use.

Bipolar disorder:

USN PHEDRACUT LIPO XT may exacerbate mania in patients with bipolar disorder. Use with caution.

Iron deficiency:

USN PHEDRACUT LIPO XT may influence iron absorption and worsen anemia in people with iron deficiency.

Sleep deprivation:

USN PHEDRACUT LIPO XT should not be taken before bedtime as it may result in sleep deprivation. USN PHEDRACUT LIPO XT is not intended as a substitute for sleep.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulant/antiplatelet medicines:

USN PHEDRACUT LIPO XT may enhance the effects of anticoagulant/antiplatelet medicines or herbal supplements. Concomitant use may increase the risk of bruising and bleeding (see section 4.4).

Antidiabetic medicines:

The use of USN PHEDRACUT LIPO XT with antidiabetic medicines or herbal supplements with hypoglycaemic effects may have an additive effect when used concomitantly (see section 4.4). Caution is advised.

Ephedrine and other stimulants:

Concomitant use of USN PHEDRACUT LIPO XT with ephedrine or other stimulants such as bitter orange extract, synephrine, octopamine and ephedra may increase blood pressure and heart rate and potentially increase the risk of serious cardiovascular adverse effects. Caution is advised.

Caffeine-containing products or foods:

The use of caffeine-containing products should be limited when taking USN PHEDRACUT LIPO XT. Use with other caffeine-containing products or foods may increase the risk of caffeine-related adverse effects. Other natural products which contain caffeine include coffee, tea, cola nut, cocoa, guarana and maté.

Monoamine oxidase inhibitors (MAOIs):

Concomitant use of USN PHEDRACUT LIPO XT with MAOIs may increase blood pressure raising effects. Caution is advised.

Hepatotoxic medicines:

Concomitant use of USN PHEDRACUT LIPO XT with hepatotoxic medicine or herbal supplements may increase the risk of liver damage. Caution is advised.

Lithium:

The concomitant use of USN PHEDRACUT LIPO XT with lithium may affect serum lithium levels. Caution is advised.

Antibiotics:

USN PHEDRACUT LIPO XT may decrease the absorption of antibiotics. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking USN PHEDRACUT LIPO XT.

4.6 Fertility, pregnancy and lactation:

Safety in pregnancy and lactation has not been established.

Total caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

4.7 Effects on ability to drive and use machines:

USN PHEDRACUT LIPO XT may cause side effects such as dizziness which can affect the ability to drive a vehicle and use machines (see section 4.8).

Caution is advised before driving a vehicle or operating machinery until the effects of USN PHEDRACUT LIPO XT are known.

4.8 Undesirable effects

USN PHEDRACUT LIPO XT is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Psychiatric disorders:

Frequency unknown: anxiety, nervousness, insomnia.

Nervous system disorders:

Frequency unknown: restlessness, dizziness, tremors, agitation, headache.

Cardiac disorders:

Frequency unknown: dysrhythmia, hypertension.

Gastrointestinal disorders:

Frequency unknown: gastric irritation, abdominal cramps, nausea, vomiting, dyspepsia, flatulence, belching, constipation, diarrhoea.

Hepato-biliary disorders:

Frequency unknown: hepatotoxicity.

Renal and urinary disorders:

Frequency unknown: diuresis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of USN PHEDRACUT LIPO XT is important. It allows continued monitoring of the benefit/risk balance of USN PHEDRACUT LIPO XT. Healthcare providers are asked to report any suspected adverse reactions to the South African Health Products Regulatory Authority (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

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). At doses of more than 600 mg per day, caffeine (as in USN PHEDRACUT LIPO XT) may cause anxiety, tachycardia (rapid heart rate), palpitations, insomnia, restlessness, nervousness, tremor and headache.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class:

D 33.7 Combination Product.

USN PHEDRACUT LIPO XT contains a variety of herbal ingredients, vitamins, minerals and caffeine which have thermogenic properties to assist weight loss as part of a weight management programme.

5.2 Pharmacokinetic properties

Caffeine is rapidly and almost completely (99 %) absorbed after oral administration. Cytochrome P450 1A2 plays a role in the metabolism of caffeine in the liver. The half-life of caffeine in healthy adults is 3 – 6 hours and is excreted in the urine. Pregnancy and oral contraceptives appear to delay caffeine clearance and smoking increases it.

Coffea robusta L. Linden (Green Coffee Bean) contains chlorogenic acids which are 50 % hydrolysed by the gut microflora after ingestion and excreted in the urine. *Camellia sinensis* (L.) Kuntze (Green Tea) may increase general levels of plasma polyphenols as well as epigallocatechin gallate (EGCG). Taking *Camellia sinensis* (L.) Kuntze (Green Tea) in the fasting state may increase plasma levels of EGCG. EGCG has an elimination half-life of approximately 5 hours and is excreted in the urine. Zinc is absorbed in the small intestines, distributed in the body in skeletal muscle and bone and mainly excreted through the faeces.

Pantothenic acid (Vitamin B₅) is the precursor of coenzyme A (CoA) and is excreted in the urine.

Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

Pyridoxine (Vitamin B₆) is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine. There is insufficient information available about the pharmacokinetic properties of *Garcinia cambogia*, Theacrine and BioPerine® *Piper nigrum* L. (Black Pepper).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Gelatine capsules (bovine)
- Magnesium stearate
- Silicon dioxide (Aerosil®).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

Store at or below 25 °C.

6.4 Special precautions for storage

Store in a dry place.

6.5 Nature and contents of container

Capsules are packed in a white HDPE bottle with a white screw-on cap and induction seal. Each bottle also contains a silica gel sachet and foam wad. Available in pack sizes of 40 and 80 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

USN (Pty) Ltd
Unit 4, Louwardia Logistics Park
cnr Nellmapius Drive & Olievenhoutbosch Road
Centurion, 1683
Pretoria

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in April 2021.

JOB: SACE_PheducutLIPOXT_All sizes		SIZE: 300mm x 363mm	
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"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing	
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			

