

PROFESSIONAL INFORMATION



USN PHEDRACUT LIPO X NIGHT

38857 P10

(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 X NIGHT capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS

Table with 4 columns: Ingredient, Per Capsule, Per Dose, and %NRV. Includes Acetyl-L-Carnitine HCl, Garcinia cambogia, Thermozone™, BioPerine®, and Chromium Picolinate.

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Size 00 white hard gelatine capsules containing an off-white to light brown powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

USN PHEDRACUT LIPO X NIGHT is indicated as a stimulant free weight loss aid, to assist weight loss as part of a weight management programme.

4.2 Posology and method of administration

- Adults: As a health 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 USN PHEDRACUT LIPO X GOLD: Take 2 capsules USN PHEDRACUT LIPO X NIGHT 30 minutes before dinner. Also take 2 capsules twice daily when taking a break from USN PHEDRACUT LIPO X GOLD (e.g. on weekends). Do not exceed the recommended daily dosage.

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 X NIGHT 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 X NIGHT at least 2 weeks prior to surgical procedures (see section 4.5).

Diabetes mellitus: USN PHEDRACUT LIPO X NIGHT 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).

Renal disease: USN PHEDRACUT LIPO X NIGHT may exacerbate renal dysfunction in patients with renal disease.

Liver disease: USN PHEDRACUT LIPO X NIGHT may worsen liver dysfunction in patients with existing liver disease.

Bipolar disorder: USN PHEDRACUT LIPO X NIGHT may exacerbate mania in patients with bipolar disorder.

Thyroid dysfunction: USN PHEDRACUT LIPO X NIGHT may exacerbate hyper- or hypothyroidism.

Epilepsy: USN PHEDRACUT LIPO X NIGHT may increase seizure frequency or severity in people with a history of seizures.

Pediatric population: The safety and efficacy of USN PHEDRACUT LIPO X NIGHT have not been established in children under the age of 18 years.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulant/antiplatelet medicines: USN PHEDRACUT LIPO X NIGHT may enhance the effects of anticoagulant/antiplatelet medicines or herbal supplements. Concomitant use may increase the risk of bruising and bleeding.

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

Hepatotoxic medicines: Concomitant use of USN PHEDRACUT LIPO X NIGHT with hepatotoxic medicines or herbal supplements may increase the risk of developing liver damage. Caution is advised.

Levothyroxine: The use of USN PHEDRACUT LIPO X NIGHT with levothyroxine may decrease serum levels of levothyroxine. Levothyroxine should be taken at least 30 minutes before or 3 – 4 hours after taking USN PHEDRACUT LIPO X NIGHT.

Antidepressant medicines: The use of USN PHEDRACUT LIPO X NIGHT with antidepressant medicines or other serotonergic medicines may increase the risk of serotonergic side effects. Caution is advised.

4.6 Fertility, pregnancy and lactation:

Safety in pregnancy and lactation has not been established. USN PHEDRACUT LIPO X NIGHT should not be taken during pregnancy or lactation.

4.7 Effects on ability to drive and use machines:

USN PHEDRACUT LIPO X NIGHT is unlikely to affect the ability to drive a vehicle and use machines. Caution is advised before driving a vehicle or operating machinery until the effects of USN PHEDRACUT LIPO X NIGHT are known.

4.8 Undesirable effects

USN PHEDRACUT LIPO X NIGHT is generally well tolerated.

Psychiatric disorders: Frequency unknown: irritability, mood changes, insomnia.

Nervous system disorders: Frequency unknown: agitation, headache.

Gastrointestinal disorders: Frequency unknown: gastrointestinal upset, nausea, vomiting, dry mouth, dyspepsia, diarrhoea.

Hepato-biliary disorders: Frequency unknown: hepatotoxicity.

Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of USN PHEDRACUT LIPO X NIGHT is important. It allows continued monitoring of the benefit/risk balance of USN PHEDRACUT LIPO X NIGHT. 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). 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 X NIGHT contains a variety of non-stimulating ingredients that may assist with weight loss as part of a weight management programme.

5.2 Pharmacokinetic properties

Acetyl L-Carnitine is mainly distributed to the muscle. The half-life of L-Carnitine is about 15 hours and is excreted in the urine.

Approximately 0,5 % to 2 % of chromium is absorbed. Chromium as chromium picolinate have increased absorption, retention and accumulation of chromium. Absorbed chromium is rapidly excreted in the urine and unabsorbed chromium in the faeces.

There is insufficient information available about the pharmacokinetics of Garcinia cambogia, Aframomum melegueta (Grains of Paradise) and BioPerine® Piper nigrum L. (Black Pepper).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Gelatine capsules (bovine)
Magnesium stearate
Potato starch
Silicon dioxide.

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

60 capsules are packed in a white HDPE container with a white screw-on cap and induction seal, packed inside a carton.

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 July 2021.

Order form for USN PHEDRACUT LIPO X NIGHT 60s. Includes fields for JOB, STOCK, COLOURS, FINISHING, and PLEASE CHECK CAREFULLY.

