

PROFESSIONAL INFORMATION



# USN PHEDRACUT SLIMPACKS

38539 PI

(powder)

**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 SLIMPACKS BERRY FLAVOUR powder  
USN PHEDRACUT SLIMPACKS MANGO-ORANGE FLAVOUR powder  
USN PHEDRACUT SLIMPACKS GRAPE FLAVOUR powder

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS	Per 5 g sachet	%NRV
<i>Garcinia cambogia</i> [fruit, extract standardised to 60 % (120 mg) hydroxycitric acid (HCA)]	200 mg	
<i>Ilex paraguariensis</i> A.St.-Hil. (Yerba Mate) [leaf; 5:1 extract providing 350 mg dried herb equivalent]	70 mg	
<i>Lycium barbarum</i> L. (Goji Berry) [fruit, 4:1 extract providing 96 mg dried herb equivalent]	24 mg	
Calcium Lactate providing Calcium (elemental)	500 mg 65 mg	5 %
Taurine	500 mg	
L-Carnitine Fumarate	200 mg	
Caffeine Anhydrous	170 mg	
N-Acetyl-L-Tyrosine	150 mg	
Medium Chain Triglyceride (MCT) powder	30 mg	
Ascorbic Acid (Vitamin C)	15 mg	15 %
Zinc Citrate providing Zinc (elemental)	4,8 mg 1,5 mg	14 %
Calcium-D-Panthenate providing Pantothenic acid (Vitamin B <sub>5</sub> )	0,9 mg 0,4 mg	8 %
Chromium Picolinate providing Chromium (elemental)	133 µg 16,5 µg	47 %

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

CONTAINS CAFFEINE (170 mg/5 g sachet).

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

### Excipients with known effects:

Contains sugar: Glucose, Fructose and Sucrose 39 mg/5 g.  
Contains sweeteners: Sodium Cyclamate 162 mg/5 g, Sucralose 68 mg/5 g, Acesulfame-K 27 mg/5 g and Sodium Saccharin 20 mg/5 g.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Powder.

USN PHEDRACUT SLIMPACKS BERRY FLAVOUR powder: Pale red powder with a berry flavour.  
USN PHEDRACUT SLIMPACKS MANGO-ORANGE FLAVOUR powder: Pale orange powder with a mango-orange flavour.  
USN PHEDRACUT SLIMPACKS GRAPE FLAVOUR powder: Pale purple powder with a grape flavour.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

USN PHEDRACUT SLIMPACKS is an energizing drink 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. USN PHEDRACUT SLIMPACKS may assist with appetite control and increased energy levels.

### 4.2 Posology and method of administration

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 serving 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 SLIMPACKS for 5 consecutive days of the week and stop use for 2 days before continuing again.
- 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.  
Hypersensitivity to lipid transfer protein (LTP) included in peaches, tomatoes, tobacco or nuts due to a cross-sensitivity with goji.

### 4.4 Special warnings and precautions for use

#### Bleeding disorders:

USN PHEDRACUT SLIMPACKS 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 SLIMPACKS at least 2 weeks prior to surgical procedures (see section 4.5).

#### Cardiac conditions:

USN PHEDRACUT SLIMPACKS 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 SLIMPACKS may also temporarily increase blood pressure when used short-term.

#### Diabetes mellitus:

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

#### Renal disease:

USN PHEDRACUT SLIMPACKS may exacerbate renal dysfunction in patients with renal disease. USN PHEDRACUT SLIMPACKS may also increase the risk of incontinence or worsen symptoms of urinary incontinence, such as urinary frequency and urgency (overactive bladder syndrome).

#### Liver disease:

USN PHEDRACUT SLIMPACKS may exacerbate liver dysfunction in patients with liver disease.

#### Bipolar disorder:

USN PHEDRACUT SLIMPACKS may exacerbate mania in patients with bipolar disorder.

#### Thyroid dysfunction:

USN PHEDRACUT SLIMPACKS may exacerbate hyperthyroidism.

#### Epilepsy:

USN PHEDRACUT SLIMPACKS may increase seizure frequency or severity in people with a history of seizures.

#### Low protein diet:

Patients following a low protein diet should consult a healthcare provider before they take USN PHEDRACUT SLIMPACKS.

#### Sleep deprivation:

Use of USN PHEDRACUT SLIMPACKS is not recommended before bedtime as it may result in sleep deprivation. USN PHEDRACUT SLIMPACKS is not intended as a substitute for sleep.

#### Contains sugar:

USN PHEDRACUT SLIMPACKS contains sugar (Glucose, Fructose and Sucrose). The additive effect of concomitantly administered products containing fructose (or sorbitol) and dietary intake of fructose (or sorbitol) should be taken into account. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take USN PHEDRACUT SLIMPACKS.

USN PHEDRACUT SLIMPACKS also contains maltodextrin. Maltodextrin has a high glycaemic index value and should be used sparingly by diabetic and/or hypoglycaemic individuals, as it may increase blood sugar levels.

#### Paediatric population

The safety and efficacy of USN PHEDRACUT SLIMPACKS have not been established in children under the age of 18 years.

### 4.5 Interaction with other medicines and other forms of interaction

#### Anticoagulant/antiplatelet medicines:

USN PHEDRACUT SLIMPACKS 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 SLIMPACKS 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 SLIMPACKS 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 SLIMPACKS. 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.

#### Hepatotoxic medicines:

Taking USN PHEDRACUT SLIMPACKS with hepatotoxic medicines or herbal supplements with hepatotoxic effects may increase the risk of developing liver damage. Caution is advised.

#### Thyroid hormones:

The use of USN PHEDRACUT SLIMPACKS 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 SLIMPACKS.

#### Antidepressant medicines:

The use of USN PHEDRACUT SLIMPACKS with antidepressant medicines or other serotonergic medicines may increase the risk of serotonergic side effects. Concomitant use of USN PHEDRACUT SLIMPACKS with Monoamine oxidase inhibitors (MAOIs) may increase blood pressure raising effects. Caution is advised.

#### Thyroid hormones:

The use of USN PHEDRACUT SLIMPACKS with thyroid hormone medicines may have additive effects. Caution is advised.

#### Lithium:

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

### 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 SLIMPACKS 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 SLIMPACKS are known.

### 4.8 Undesirable effects

USN PHEDRACUT SLIMPACKS is generally well tolerated.

#### Immune system disorders:

*Frequency unknown:* hypersensitivity and/or allergic reactions.

#### Psychiatric disorders:

*Frequency unknown:* anxiety, nervousness, irritability, insomnia.

#### Nervous system disorders:

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

#### Cardiac disorders:

*Frequency unknown:* dysrhythmia, hypertension.

#### Vascular disorders:

*Frequency unknown:* flushing.

#### Gastrointestinal disorders:

*Frequency unknown:* gastric irritation, stomach upset, nausea, vomiting, abdominal pain, 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 SLIMPACKS is important. It allows continued monitoring of the benefit/risk balance of USN PHEDRACUT SLIMPACKS. 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 SLIMPACKS contains a variety of herbal ingredients, vitamins, minerals, amino acids and caffeine to assist with weight loss as part of a weight management programme.

### 5.2 Pharmacokinetic properties

Hydroxycitric acid (HCA) is the principal acid in *Garcinia cambogia* 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.

Polyphenols, including hydroxycinnamic acids, are partially absorbed after oral consumption of Yerba mate. These polyphenols are metabolised by the colonic microbiota, which can delay absorption of certain polyphenols such as dihydrocaffeic, dihydroferulic, and dihydrocoumaric acids. High concentrations of caffeine and theobromine were found in the placenta, cord serum, neonatal urine, maternal and neonatal hair, meconium, and breast milk from a mother who reported drinking yerba mate during pregnancy.

Goji berries contain beta-sitosterol, betaine, carotenoids, primarily lutein, zeaxanthin, p-coumaric acid, beta-carotene, polysaccharides, niacin, pyridoxine, ascorbic acid and various minerals.

Calcium absorption is affected by several factors like age, race, environmental and dietary conditions. Dietary calcium absorption is inversely correlated with total dietary calcium, dietary fibre, alcohol intake and physical activity. Calcium is distributed in the bones and teeth and excreted via the urine and faeces.

Taurine is an amino acid which is normally synthesised in the human body in adequate amounts by oxidation and decarboxylation of cysteine. Taurine has been reported to decrease oxidative stress and it is possible that it prevents increases in carbonyl protein and lipoperoxide levels which contribute to muscle soreness. Taurine is conjugated to bile acids, and it is also excreted in the urine.

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

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.

Peak plasma levels of tyrosine occur within 1,5 to 3 hours after oral intake. Tyrosine is converted to L-dopa, dopamine, noradrenaline and adrenaline in the brain by tyrosine hydroxylase. Tyrosine is transported across the blood brain barrier by the large neutral amino acid (LNAA) transporter and excreted in the urine as noradrenaline, adrenaline, dopamine, 3-methoxy-4-hydroxyphenylglycol, vanillylmandelic acid and homovanillic acid in men.

Medium chain triglycerides (MCTs) are efficiently absorbed. At physiological pH, MCTs are weak electrolytes and highly ionised, which increases their solubility. Unlike long chain triglycerides (dietary fat), MCTs don't require the intestinal lymphatic system or bile salts for absorption. They are absorbed directly into the portal circulation. MCTs are metabolized primarily in the liver by beta-oxidation.

Vitamin C is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through urine.

Vitamin B<sub>5</sub> is an essential B vitamin. It is absorbed from the small intestines and widely distributed through the body. About 70 % is excreted unchanged in the urine, and 30 % in the faeces.

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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Acesulfame-K  
Colourant (Red, Orange or Purple)  
Flavour (Berry, Mango-orange or Grape)  
Fructooligosaccharides (containing Glucose, Fructose and Sucrose)  
Malic acid  
Maltodextrin  
Sodium Cyclamate  
Sodium Saccharin  
Sucralose.

### 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

White plastic sachets with 5 g powder, packed inside a carton. Pack size: 20 sachets per 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 Nellmapus Drive & Olivevouthbosch Road  
Centurion, 1683  
Pretoria

## 8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

## 10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in June 2021.

PHE041-065-071/PI-PIL/A

<b>JOB:</b> SAHC_PheducrutSlimpacks PI/PIL	<b>SIZE:</b> 300mm x 403mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOURS:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Darning <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b>	<small>Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.</small>

