

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:



USN PHEDRACUT BURN XT ONE-A-DAY

(capsules)

COMPOSITION:

Active ingredients:

	Per Capsule	*%NRV
Apple Cider Vinegar Powder	300 mg	
Total Caffeine (from Caffeine Anhydrous & Green Tea Extract)	250 mg	
<i>Camellia sinensis</i> (L.) Kuntze (Green Tea Extract) [leaves, extract standardised to EGCG 40 %]	225 mg	
<i>Theobroma cacao</i> L. (Cocoa Extract) [fruit, extract standardised to Theobromine 10 %]	60 mg	
<i>Aframomum melegueta</i> K.Schum. (Grains of Paradise) [seed, 10:1 extract]	40 mg	
Chromium picolinate providing Chromium (elemental)	1668 µg 200 µg	571 %

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

Other ingredients: Colloidal silicon dioxide (Aerosil®), magnesium stearate, vegi capsules.

Sugar free

CATEGORY AND CLASS:

D 33.7 Combination Product

PHARMACOLOGICAL ACTION:

Apple Cider Vinegar Powder: Apple cider vinegar may significantly increase postprandial insulin sensitivity and reduces postprandial flux in insulin levels. Apple cider vinegar can also affect glucose levels by delaying the gastric emptying rating. Acetic acid in vinegar also seems to suppress disaccharidase activity and increase glucose-6-phosphate levels in skeletal muscle. Therefore, it might also work by preventing the breakdown of carbohydrates into sugars.

Caffeine: 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.

Green Tea Extract: The polyphenols in green tea are antioxidant compounds. In human research, green tea polyphenols improved muscular endurance and prevented a rise in plasma creatine kinase activity seen in the placebo group following exercise. Studies suggest that green tea may modulate blood sugar levels and affect levels of insulin and insulin resistance. Dietary supplementation with EGCG, one of the catechins, increased compliance with diet in overweight but otherwise healthy subjects.

Cocoa (*Theobroma cacao*) extract: Cocoa extract contains theobromine as one of the active constituents. The main mechanism of action of theobromine are inhibition of phosphodiesterases and blockade of adenosine receptors. Research showed that theobromine could help with an increase in fat metabolism and suppressing fat absorption. Theobromine is a mild stimulant and diuretic; therefore, it may increase energy for activity and decrease water weight. One study showed that an improved insulin sensitivity from theobromine may help with weight loss in individuals.

Grains of Paradise (*Aframomum melegueta*) seed extract: Grains of Paradise (*Aframomum melegueta*), 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 BURN XT ONE-A-DAY is indicated as a weight loss aid combined with a balanced, energy-controlled eating plan and regular physical activity.

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 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 BURN XT ONE-A-DAY** might interfere with surgical procedures by increasing heart rate and blood pressure.
- Use with caution in patients with diabetes. **USN PHEDRACUT BURN XT ONE-A-DAY** can influence blood sugar levels in diabetic patients; monitor closely. Dose adjustments to antidiabetic medication might be necessary.
- USN PHEDRACUT BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY** might exacerbate renal dysfunction.
- Use with caution in patients with hypokalaemia; apple cider vinegar might cause potassium loss and worsen hypokalaemia.
- Use with caution in patients with Irritable Bowel Syndrome (IBS), caffeine can exacerbate diarrhoea and might worsen the symptoms of IBS.
- Use with caution in patients with Gastroesophageal Reflux Disease (GERD), cocoa reduces lower esophageal sphincter pressure and could exacerbate symptoms of GERD.
- Use with caution in patients that suffer from regular migraine headaches. Cocoa might trigger migraines in sensitive individuals.
- Do not exceed the daily recommended dose.

INTERACTIONS:

- Anticoagulant/antiplatelet medicine:** **USN PHEDRACUT BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY** 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.
- Digoxin:** Apple cider vinegar could decrease potassium levels, increasing the risk of toxicity for cardiovascular medicine such as digoxin.
- Diuretic medicine:** The use of apple cider vinegar along with potassium-depleting diuretics might have an increased risk for hypokalaemia. Some diuretics that can deplete potassium include furosemide, hydrochlorothiazide, chlorthalidone, and others.
- Ephedrine and other stimulants:** The use of **USN PHEDRACUT BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY** with MAOIs. MAOIs include phenelzine, tranylcypromine and others.
- Levothyroxine:** The use of **USN PHEDRACUT BURN XT ONE-A-DAY** 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 BURN XT ONE-A-DAY**.
- 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 BURN XT ONE-A-DAY**.
- 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 BURN XT ONE-A-DAY**.
- 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 BURN XT ONE-A-DAY**.

HUMAN REPRODUCTION:

Safety has not been established for use during pregnancy and lactation. Do not use **USN PHEDRACUT BURN XT ONE-A-DAY** if you are pregnant or lactating.

DOSAGE AND DIRECTIONS FOR USE:

Adults: As a dietary supplement, take 1 vegi capsule in the morning on an empty stomach with a glass of water, ideally 30 minutes before morning exercise (or 30-60 minute walk). Consume 6-8 glasses of water per day and reduce carbohydrate consumption. Not suitable for use after 4 pm.

Take **USN PHEDRACUT BURN XT ONE-A-DAY** for 5 consecutive days of the week and stop use for 2 days before continuing again.

Do not exceed the recommended daily dosage.

SIDE EFFECTS:

The following side effects may be associated with the use of **USN PHEDRACUT BURN XT ONE-A-DAY**:

- Blood disorders:** *Frequency unknown* – Increased bleeding risk.
- Immune system disorders:** *Frequency unknown* – Hypersensitivity and/or allergic reactions.
- Endocrine disorders:** *Frequency unknown* – Hypoglycaemia, hypokalaemia, hyperreninaemia.
- Psychiatric disorders:** *Frequency unknown* – Anxiety, agitation, mood changes.
- Nervous system disorders:** *Frequency unknown* – Dizziness, insomnia, headache, migraine, 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, borborygmi, 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:

White vegi capsules containing light brown powder with white and dark speckles.

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,
21 Karee Street, Irene Ext 54, 0157
Tel: 0861 111 876

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:


February 2020.

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.

PHE080/PI-PI/LA

JOB: SACE_PhedraCut BurnXT_OneDay	SIZE: 300mm x 426mm
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"/> Doming <input type="checkbox"/> Embossing

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:



USN PHEDRACUT BURN XT ONE-A-DAY

(capsules)

Read all of this leaflet carefully because it contains important information for you.

USN PHEDRACUT BURN XT ONE-A-DAY is available without a doctor's prescription. Nevertheless, you still need to use USN PHEDRACUT BURN XT ONE-A-DAY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share USN PHEDRACUT BURN XT ONE-A-DAY with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT USN PHEDRACUT BURN XT ONE-A-DAY CONTAINS: Active ingredients:

Active ingredients:	Per Capsule	%NRV
Apple Cider Vinegar Powder	300 mg	
Total Caffeine (from Caffeine Anhydrous & Green Tea Extract)	250 mg	
<i>Camellia sinensis</i> (L.) Kuntze (Green Tea Extract) [leaves, extract standardised to EGCG 40 %]	225 mg	
<i>Theobroma cacao</i> L. (Cocoa Extract) [fruit, extract standardised to Theobromine 10 %]	60 mg	
<i>Aframomum melegueta</i> K.Schum. (Grains of Paradise) [seed, 10:1 extract]	40 mg	
Chromium picolinate providing Chromium (elemental)	1668 µg	571 %
	200 µg	

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

Other ingredients: Colloidal silicon dioxide (Aerosil®), magnesium stearate, vegi capsules.

Sugar free

2. WHAT USN PHEDRACUT BURN XT ONE-A-DAY IS USED FOR:

USN PHEDRACUT BURN XT ONE-A-DAY is indicated as a weight loss aid combined with a balanced, energy-controlled eating plan and regular physical activity.

3. BEFORE YOU TAKE USN PHEDRACUT BURN XT ONE-A-DAY:

Do not take USN PHEDRACUT BURN XT ONE-A-DAY:

- If you are hypersensitive (allergic) to any of the active or inactive ingredients (see WHAT USN PHEDRACUT BURN XT ONE-A-DAY CONTAINS). This includes an allergy to ginger, as Grains of Paradise extract is a member of the *Zingiberaceae* (ginger) family.
- If you are pregnant or breastfeeding your baby (see Pregnancy and Breastfeeding).
- If you are under 18 years of age.

Take special care with USN PHEDRACUT BURN XT ONE-A-DAY:

- If you have high blood pressure. Caffeine can temporarily increase blood pressure.
- If you have any cardiac conditions. Caffeine, especially taken in high doses, can lead to irregular heartbeat in individuals sensitive to caffeine.
- If you are having elective surgery within two weeks. The stimulant effects of USN PHEDRACUT BURN XT ONE-A-DAY might interfere with surgical procedures by increasing heart rate and blood pressure.
- If you have diabetes. USN PHEDRACUT BURN XT ONE-A-DAY can influence blood sugar levels. Dose adjustments to antidiabetic medicine might be necessary. Monitor closely.
- If you have a bleeding disorder. USN PHEDRACUT BURN XT ONE-A-DAY can inhibit platelet aggregation and increase the risk of bruising and bleeding; use with caution.
- If you have an anxiety disorder, the caffeine might worsen the symptoms.
- If you have a liver disease. USN PHEDRACUT BURN XT ONE-A-DAY might worsen liver dysfunction. Use with caution.
- If you have epilepsy. Caffeine can increase the risk for seizures (fits) and can reduce the effectiveness of some anticonvulsant medicine.
- If you have narrow-angle glaucoma. USN PHEDRACUT BURN XT ONE-A-DAY can temporarily increase intraocular pressure due to the caffeine content.
- If you have a kidney disease, USN PHEDRACUT BURN XT ONE-A-DAY might worsen kidney dysfunction. Use with caution.
- If you have hypokalaemia (low potassium levels in the blood), apple cider vinegar might cause potassium loss and worsen the condition.
- If you have Irritable Bowel Syndrome (IBS), caffeine can cause diarrhea and might worsen the symptoms of IBS.
- If you have Gastroesophageal Reflux Disease (GERD), cocoa reduces lower esophageal sphincter pressure and could worsen symptoms of GERD.
- If you suffer from regular migraine headaches, cocoa might trigger migraines in sensitive individuals.
- Do not exceed the daily recommended dose.

Taking USN PHEDRACUT BURN XT ONE-A-DAY with food and drink:

- USN PHEDRACUT BURN XT ONE-A-DAY should be taken on an empty stomach with a glass of water.

Pregnancy and Breastfeeding:

- Safety has not been established for use during pregnancy and breastfeeding. Avoid use.

Driving and using machinery:

It is unlikely that USN PHEDRACUT BURN XT ONE-A-DAY will affect your ability to drive a vehicle or operate machinery requiring your attention.

Taking other medicines with USN PHEDRACUT BURN XT ONE-A-DAY:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are on any of the following medicine or treatment, you should discuss the use of USN PHEDRACUT BURN XT ONE-A-DAY with your doctor or pharmacist first:

- Anticoagulant/antiplatelet medicine (such as aspirin, clopidogrel, heparin, indomethacin and warfarin), as USN PHEDRACUT BURN XT ONE-A-DAY can inhibit platelet aggregation and might increase the risk of bleeding when used with these medicines.
- Anticonvulsant medicine (such as carbamazepine, ethosuximide, felbamate, phenytoin and valproate), as the caffeine in USN PHEDRACUT BURN XT ONE-A-DAY can lower the effect of these medicines and increase the risk of seizures (fits).
- Antidiabetic medicine (such as glicemipiride, insulin, metformin, etc.). Use of these medicines with USN PHEDRACUT BURN XT ONE-A-DAY might interfere with blood glucose control and increase the risk of low blood sugar.
- Digoxin, as apple cider vinegar could decrease potassium levels and increase the risk of toxicity for cardiovascular medicine such as digoxin.
- Diuretic medicine (such as furosemide, hydrochlorothiazide, chlorthalidone, etc.). The use of apple cider vinegar along with these potassium-depleting diuretics might increase the risk for hypokalaemia.
- Ephedrine and other stimulants (such as pseudoephedrine, phenylpropanolamine, etc.). These stimulants can increase the risk of stimulatory adverse effects when used with USN PHEDRACUT BURN XT ONE-A-DAY. The use of ephedrine with caffeine might increase the risk of serious life-threatening adverse effects such as high blood pressure, heart attack, stroke, fits and death. Avoid using together.
- Monoamine oxidase inhibitors (MAOIs) (such as phenelzine, tranylcypromine and others), as these medicines used with caffeine might increase blood pressure and could cause a hypertensive crisis. Avoid using together.
- Levothyroxine, as the chromium in USN PHEDRACUT BURN XT ONE-A-DAY can bind to levothyroxine in the intestinal tract and cause serum levels of levothyroxine to decrease. Take levothyroxine at least 30 minutes before or 3-4 hours after taking USN PHEDRACUT BURN XT ONE-A-DAY.
- Herbs and supplements with stimulant properties (bitter orange supplements as well as other caffeine-containing herbs and supplements such as coffee, guarana, maté, etc.), can increase the risk of high blood pressure and cardiovascular adverse effects when used with USN PHEDRACUT BURN XT ONE-A-DAY.
- Herbs and supplements with anticoagulant/antiplatelet properties (such as garlic, ginger, turmeric and others), can increase the risk of bruising and bleeding when used with USN PHEDRACUT BURN XT ONE-A-DAY.
- Herbs and supplements with hypoglycaemic potential (such as fenugreek, garlic, Panax ginseng and others), as these supplements can increase the risk of low blood sugar when used with USN PHEDRACUT BURN XT ONE-A-DAY.

4. HOW TO TAKE USN PHEDRACUT BURN XT ONE-A-DAY:

Do not share medicines prescribed for you with any other person. Always take USN PHEDRACUT BURN XT ONE-A-DAY exactly as directed. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

- *Adults:* As a dietary supplement, take 1 vegi capsule in the morning on an empty stomach with a glass of water, ideally 30 minutes before morning exercise (or 30-60 minute walk). Consume 6-8 glasses of water per day and reduce carbohydrate consumption. Not suitable for use after 4 pm.
- Take USN PHEDRACUT BURN XT ONE-A-DAY for 5 consecutive days of the week and stop use for 2 days before continuing again.

Do not exceed the recommended daily dosage.

If you take more USN PHEDRACUT BURN XT ONE-A-DAY than you should:

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take USN PHEDRACUT BURN XT ONE-A-DAY:

Take the missed dose as soon as you remember. If it is almost time for your next dose, do not take the missed dose but simply take your next dose at the normal time. Do not take a double dose to make up the one you missed.

5. POSSIBLE SIDE EFFECTS:

- USN PHEDRACUT BURN XT ONE-A-DAY can have side effects.
- Not all side effects reported for USN PHEDRACUT BURN XT ONE-A-DAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.
- If any of the following happens, stop taking USN PHEDRACUT BURN XT ONE-A-DAY and tell your doctor immediately or go to the casualty department at your nearest hospital:
 - Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
 - Rash or itching.
 - Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to USN PHEDRACUT BURN XT ONE-A-DAY. You may need urgent medical attention or hospitalisation.

- Tell your doctor immediately or go to the casualty department at your nearest hospital if any of the following happens:
 - Seizure (fit).
 - Stroke/ischemic stroke.
 - Heart attack.
 - Angina (chest pain).

These are all serious side effects. You may need urgent medical attention.

- Tell your doctor as soon as possible if you notice any of the following:
 - High blood pressure.
 - Increased/irregular heart rate.
 - Increased bleeding.
 - Low blood sugar.
 - Increased anxiety/agitation*.
 - Severe mood changes.
 - Nervousness, restlessness.
 - Dizziness.
 - Insomnia (difficulty falling/staying asleep).
 - Headache*.
 - Migraine.
 - Abdominal cramps, gastric irritation.
 - Abdominal bloating, flatulence (gas), constipation.
 - Borborygmi (stomach noises).
 - Nausea*, vomiting.
 - Diarrhoea.
 - Decreased appetite.
 - Dyspepsia, reflux, heartburn.
 - Raised, itchy rash (urticaria).
 - Muscular tremors.
 - Increased production of urine (diuresis).
 - Kidney pain.

*These side effects commonly occur with slimming agents that contain stimulants and usually subside within 2 weeks of use.

- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF USN PHEDRACUT BURN XT ONE-A-DAY:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Do not store in the bathroom.
- Store in its original container.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the container.
- Do not use USN PHEDRACUT BURN XT ONE-A-DAY if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF USN PHEDRACUT BURN XT ONE-A-DAY:

White HDPE plastic container with a white USN lid, containing 60 capsules, packed inside a carton.

8. IDENTIFICATION OF USN PHEDRACUT BURN XT ONE-A-DAY:

White vegi capsules containing light brown powder with white and dark speckles.

9. REGISTRATION NUMBER:

To be allocated by the Authority.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

USN Pty (Ltd)
Building C, Southdowns Office Park, 2nd Floor,
21 Karee Street, Irene Ext 54, 0157
Tel: 0861 111 876

11. DATE OF PUBLICATION:

February 2020.

12. 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.

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS:

Nie geskeduleer nie.

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:



USN PHEDRACUT BURN XT ONE-A-DAY

(kapsules)

Lees die hele pamflet noukeurig deur, aangesien dit belangrike inligting vir u bevat.

USN PHEDRACUT BURN XT ONE-A-DAY is beskikbaar sonder 'n dokter se voorskryf. Nietemin moet u steeds USN PHEDRACUT BURN XT ONE-A-DAY versigtig gebruik om die beste resultate te verkry.

- Bewaar hierdie pamflet. U mag dit dalk weer moet lees.
- Moenie USN PHEDRACUT BURN XT ONE-A-DAY met enige ander persoon deel nie.
- Vra u apteker indien u verdere inligting of advies benodig.

1. WAT USN PHEDRACUT BURN XT ONE-A-DAY BEVAT: Aktiewe bestanddele:

Aktiewe bestanddele:	Per Kapsule	%Nrv
Appelasy'n Poel	300 mg	
Totale Kafieien (Van Anhidriese Kafieien & Groentee-ekstrak)	250 mg	
<i>Camellia sinensis</i> (L.) Kuntze (Groentee-ekstrak) [blare, ekstrak gestandaardiseer tot EGCG 40 %]	225 mg	
<i>Theobroma cacao</i> L. (Kakao-ekstrak) [vrug, ekstrak gestandaardiseer tot Teobromien 10 %]	60 mg	
<i>Aframomum melegueta</i> K.Schum. (Grains of Paradise) [saad, 10:1 ekstrak]	40 mg	
Chroompikolinaat verskaf Chroom (elementele)	1668 µg	571 %
	200 µg	

*%Nutriëntverwysingswaardes (Nrvs) vir individue 4 jaar en ouer (2010).

Ander bestanddele: Kolloïdale silikondioksied (Aerosil®), magnesiumstearaat, vegikapsules.

Suikervry

2. WAARVOOR USN PHEDRACUT BURN XT ONE-A-DAY GEBRUIK WORD:

USN PHEDRACUT BURN XT ONE-A-DAY word aangedui as 'n gewigsverlieshulpmiddel gekombineer met 'n gebalanseerde, energiebeperkte eetplan en gereelde fisieke aktiwiteit.

3. VOOR U USN PHEDRACUT BURN XT ONE-A-DAY NEEM:

Moenie USN PHEDRACUT BURN XT ONE-A-DAY neem:

- Indien u hipersensitief (allergies) is vir enige van die aktiewe of onaktiewe bestanddele (sien WAT USN PHEDRACUT BURN XT ONE-A-DAY BEVAT). Dit sluit in 'n allergie vir gemmer, aangesien Grains of Paradise 'n lid is van die *Zingiberaceae* (gemmer) familie.
- Indien u swanger is of u baba borsvoed (sien Swangerskap en Borsvoeding).
- Indien u jonger as 18 jaar is.

Neem spesiale sorg met USN PHEDRACUT BURN XT ONE-A-DAY:

- Indien u aan hoë bloeddruk ly. Kafieien kan bloeddruk tydelik verhoog.
- Indien u aan enige hartaestand ly. Kafieien, veral wanneer dit in hoë dosisse geneem word, kan lei tot onreëlmatige hartklop in individue wat sensitief is vir kafieien.
- Indien u binne twee weke elektriese chirurgie ondergaan. Die stimulantefeek van USN PHEDRACUT BURN XT ONE-A-DAY mag inmeng met chirurgiese prosedures deur hartklop en bloeddruk te verhoog.
- Indien u 'n diabetes is, kan USN PHEDRACUT BURN XT ONE-A-DAY bloedsuikervlakke beïnvloed. Dosisaanpassings ten opsigte van antidiabetiese medisyne mag nodig wees. Monitor noukeurig.
- Indien u aan 'n bloedingsiekte ly, mag USN PHEDRACUT BURN XT ONE-A-DAY die sameklomp van bloedplaatjies inhibeer en sodoende die risiko van kneusing en bloeding verhoog; gebruik met omsigtigheid.
- Indien u aan 'n angusversteuring ly, mag die kafieien die simptome vererger.
- Indien u aan 'n lewersiekte ly, mag USN PHEDRACUT BURN XT ONE-A-DAY leverdiefunksie vererger. Gebruik met omsigtigheid.
- Indien u 'n epilepsietjyer is. Kafieien kan die risiko vir konvulsies verhoog en die effektiwiteit van sommige antikonvulsiewe middels verminder.
- Indien u nouhoekgloukoom het, kan USN PHEDRACUT BURN XT ONE-A-DAY intraokulêre druk tydelik verhoog te wryte aan die kafieieninhoud.
- Indien u 'n niersiekte ly, mag USN PHEDRACUT BURN XT ONE-A-DAY nierdiefunksie vererger. Gebruik met omsigtigheid.
- Indien u hipokalemie (lae kaliumvlakke in die bloed) het, appelasy'n kan kaliumverlies veroorsaak en die kondisie vererger.
- Indien u Prikkelbare Dermsindroom (PDS) het, kafieien kan diarree veroorsaak en die simptome van PDS vererger.
- Indien u Gastroesofageale Refluksiekte (GERS) het, kakao verlaag laer esofageale sfinkterdruk en kan simptome van GERS vererger.
- Kdi u aan gereelde migraine-hoofpyn ly, kan kakao migraine veroorsaak in sensitiewe persone.
- Moet nie die voorgeskrewe daaglikse dosering oorskry nie.

Neem van USN PHEDRACUT BURN XT ONE-A-DAY met voedsel en drank:

- USN PHEDRACUT BURN XT ONE-A-DAY moet op 'n leë maag geneem word met 'n glas water.

Swangerskap en Borsvoeding:

- Die veiligheid van die gebruik van hierdie produk tydens swangerskap en borsvoeding is nie vasgestel nie. Vermry gebruik.

Bestuur en gebruik van masjinerie:

Dit is onwaarskynlik dat USN PHEDRACUT BURN XT ONE-A-DAY u vermoë sal beïnvloed om 'n voertuig te bestuur of masjinerie te gebruik wat u aandag verg.

Die neem van ander medikasie saam met USN PHEDRACUT BURN XT ONE-A-DAY:

Stel altyd u gesondheidsorgeskundige daarvan in kennis indien u enige ander medikasie gebruik (Dit sluit aanvullende of tradisionele medikasie in).

Indien u enige van die volgende medisyne gebruik of behandeling ondergaan, bespreek eers die gebruik van USN PHEDRACUT BURN XT ONE-A-DAY met u dokter of apteker:

- Anti-stolmiddels/antiplaatjiesmedisyne (soos aspirien, klopidogrel, heparien, indometasien en warfarien), aangesien USN PHEDRACUT BURN XT ONE-A-DAY die sameklomp van bloedplaatjies kan inhibeer en die risiko van bloeding mag verhoog indien dit saam met hierdie medisyne geneem word.
- Antikonvulsiewe middels (soos karbamasepien, etosuksimied, felbamaat, fenitioien en valproaat), aangesien die kafieien in USN PHEDRACUT BURN XT ONE-A-DAY die effek van hierdie medisyne kan verminder en die risiko van konvulsies verhoog.
- Antidiabetiese medisyne (soos glicemipried, insulien, metformien, ens.). Gebruik van hierdie medisyne saam met USN PHEDRACUT BURN XT ONE-A-DAY mag inmeng met bloedglukosebeheer en die risiko van lae bloedsuiker verhoog.
- Digoksien, aangesien appelasyn kaliumvlakke kan verlaag en die risiko van toksisiteit vir kardiovaskulêre medisyne, soos digoksien, verhoog.
- Diuretikum medisyne (soos furosemied, hidrochlooritasied, chloorotalidon, ens.). Die gebruik van appelasyn saam met hierdie kaliumverlagende diuretika kan die risiko vir hipokalemie verhoog.
- Eledrien en ander stimulantie (soos pseudo-efedrien, fenielpropanolamien, ens.). Hierdie stimulantie kan die risiko van stimulerende nadelige effekte verhoog wanneer saam met USN PHEDRACUT BURN XT ONE-A-DAY gebruik. Die gebruik van eledrien saam met kafieien mag die risiko verhoog van ernstige lewensbedreigende nadelige effekte soos hoë bloeddruk, hartaanval, beroerte, konvulsies en sterfte. Vermry saamlopende gebruik.
- Monoamienoksidaseremmers (MAOIs) (soos fenelsien, trianielsipromien en ander), aangesien hierdie medisyne gebruik saam met kafieien bloeddruk mag verhoog en 'n hipertensiewe krisis mag veroorsaak. Vermry saamlopende gebruik.
- Levotiroksien, aangesien die chroom in USN PHEDRACUT BURN XT ONE-A-DAY kan bind met die levotiroksien in die dermkanaal en 'n verlagting in die levotiroksien serumvlakke kan veroorsaak. Neem levotiroksien ten minste 30 minute voor of 3-4 ure na die neem van USN PHEDRACUT BURN XT ONE-A-DAY.
- Kruie en aanvullings met stimulantieenskappe (bitterlemoenaanvullings sowel as ander kafieienbevattende kruie en aanvullings soos koffie, guarana, maté, ens.) kan die risiko van hoë bloeddruk en kardiovaskulêre nadelige effekte verhoog wanneer saam met USN PHEDRACUT BURN XT ONE-A-DAY gebruik.
- Kruie en aanvullings met anti-stol/antiplaatjies eenskappe (soos knoffel, gemmer, borrie, ens.) kan die risiko van kneusing en bloeding verhoog indien saam met USN PHEDRACUT BURN XT ONE-A-DAY gebruik word.
- Kruie en aanvullings met hipoglukemiese potensiaal (soos fenegriek, knoffel, Panax ginseng, ens.), aangesien hierdie aanvullings die risiko van lae bloedsuiker kan verhoog indien saam met USN PHEDRACUT BURN XT ONE-A-DAY gebruik word.

4. HOE OM USN PHEDRACUT BURN XT ONE-A-DAY TE NEEM:

Moenie medikasie wat vir u voorgeskryf is met enige ander persoon deel nie. Neem altyd USN PHEDRACUT BURN XT ONE-A-DAY presies soos voorgeskryf. Raadpleeg u dokter of apteker indien u onseker is.

Die gewone dosering is:

- *Volwassenes:* As 'n dieetaanvulling, neem 1 vegikapsule in die oggend op 'n leë maag met 'n glas water, verkieslik 30 minute voor oggend oefensessie (of 30-60 minute stap). Drink 6-8 glase water per dag en verminder koolhidraat innam. Nie geskik vir gebruik na 4 nm.
- Neem PHEDRACUT BURN XT ONE-A-DAY vir 5 opeenvolgende dae van die week, gevolg deur 'n 2-dag onderbreking, voordat die siklus weer voortgesit word.

Moenie die aanbevole daaglikse dosering oorskry nie.

Indien u meer USN PHEDRACUT BURN XT ONE-A-DAY neem as wat u veronderstel is:

In die geval van oordosering, raadpleeg u dokter of apteker. Indien daar nie een beskikbaar is nie, kontak u naaste hospital of gifbeheersentrum.

Indien u vergeet om USN PHEDRACUT BURN XT ONE-A-DAY te neem:

Neem die dosis wat u oorgeslaan het sodra u onthou. Indien dit amper tyd is vir die volgende dosis, moenie die vergete dosis neem nie, maar neem die volgende dosis die normale tyd. Moenie 'n dubbele dosis neem om op te maak vir die vergete individuele dosis nie.

5. MOONTLIKE NEWE-EFFEKTE:

- USN PHEDRACUT BURN XT ONE-A-DAY kan nuwe-effekte hê.
- Nie alle nuwe-effekte van USN PHEDRACUT BURN XT ONE-A-DAY wat aangemeld is, word by hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige ongewenste effekte ervaar ervaar u hierdie medisyne gebruik, raadpleeg u gesondheidsorgeskundige vir advies.
- Indien enige van die volgende gebeur, staak USN PHEDRACUT BURN XT ONE-A-DAY se gebruik en stel u dokter onmiddellik in kennis of gaan na die ongevalle-afdeling by u naaste hospital:
 - Swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling mag veroorsaak.
 - Uitslag of jeukerigheid.
 - Flou word.

Al hierdie nuwe-effekte is baie ernstig van aard. Indien u hierdie nuwe-effekte ervaar, het u dalk 'n ernstige allergiese reaksie tot USN PHEDRACUT BURN XT ONE-A-DAY gehad. U mag dringende mediese aandag of hospitalisasie benodig.

JOB:	SIZE:
SACE_PhedraCut BurnXT_OneaDay	300mm x 426mm
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 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

PHE080/PI-PI/LA