

PROFESSIONAL INFORMATION

SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME AND DOSAGE FORM:

USN®

32144 P16

USN PHEDRACUT LIPO X BLACK

(capsules)

COMPOSITION:

| Active ingredients: | Per Capsule | Per Dose | **%NRV |
|---|-----------------|------------------|--------|
| Sinetrol® Xpur (20 % Naringin) | 225 mg | 450 mg | |
| Total Caffeine (from Caffeine Anhydrous & Sinetrol® Xpur) | 100 mg | 200 mg | |
| <i>Coleus forskohlii</i> extract [root; extract standardised to Forskolin 1 %] | 50 mg | 100 mg | |
| L-Theanine | 50 mg | 100 mg | |
| Dynamine™ (40 % Methylberine) | 31,3 mg | 62,5 mg | |
| <i>Aframomum melegueta</i> (Grains of Paradise) extract [seed; 10:1 extract] | 25 mg | 50 mg | |
| Theacrine 99 % | 10 mg | 20 mg | |
| Chromium picolinate providing Chromium (elemental) | 417 µg 50 µg | 834 µg 100 µg | 286 % |

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

Other ingredients: Bovine gelatine capsules, magnesium stearate, silica (Aerosil®).

Sugar Free

CATEGORY AND CLASS:
D 33.7 Combination Product

PHARMACOLOGICAL ACTION:

Sinetrol® Xpur: The proprietary formula of Sinetrol® Xpur provides a synergy of bioactive polyphenols known for their lipolytic action. It includes naringin as main active compound extracted from citrus of the Mediterranean shores: sweet orange, blood orange & grapefruit. The activity of Sinetrol® Xpur is enhanced with natural caffeine from guarana.

Sinetrol® Xpur helps stimulate lipolysis through the inhibition of phosphodiesterase 4 (PDE-4)3,4, the enzyme that catalyses the hydrolysis of cAMP. In addition, polyphenols in Sinetrol® Xpur have been reported to help induce the expression of fatty acid oxidation genes, which encourage the metabolism toward the use of free fatty acids to produce additional energy yielding.

Caffeine Anhydrous: 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.

***Coleus forskohlii* root extract:** The main bioactive ingredient in *Coleus forskohlii* is called forskolin. Forskolin increases cellular levels of a molecule called cyclic adenosine monophosphate (cAMP). Elevated cAMP levels are associated with increased rates of fat loss and can improve the effects of other fat burning compounds.

L-Theanine: L-Theanine may help to temporarily promote relaxation. The anxiolytic effects might be due to its effects on glutamate receptors and the possibility it increases inhibitory neurotransmitters such as glycine or gamma-aminobutyric acid (GABA). Theanine's improvement in certain components of cognitive function may be secondary to its effects on alpha-wave activity. Theta waves also indicate cognitive alertness. Research also suggests theanine may act synergistically with caffeine and other constituents in green tea to assist with weight loss.

Dynamine™ (40 % Methylberine): The main active ingredient in Dynamine™ is methylberine which is a pure alkaloid which is naturally occurring and fast-acting. Its molecular formula is 2-methoxy-1,7,9 Tetramethyluric acid. Due to its specific molecular formula, it can more easily cross membranes for overall better absorption rates and delivery.

Dynamine™ works by preventing adenosine from binding to its receptors – which causes sleepiness and fatigue. By blocking the process, the supplement can cause an increase in physical energy and mental alertness. Dynamine™ also enhances the effect of dopamine in the body, which helps boost memory, cognitive sharpness and feelings of happiness.

***Aframomum melegueta* (Grains of Paradise) 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.

Theacrine: Theacrine is a naturally occurring purine alkaloid that is similar to caffeine. Theacrine's multi-faceted effects come from the reactions between the two neural pathways: dopaminergic and adenosinergic. By affecting these major pathways and supporting other neurotransmitters, Theacrine increases energy without irritability and enables competitive athletes and active individuals to better their physical and mental performance.

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 LIPO X BLACK is indicated as a thermogenic agent that provides added energy as an 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 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 LIPO X BLACK** might interfere with surgical procedures by increasing heart rate and blood pressure.
- Use with caution in patients with diabetes. **USN PHEDRACUT LIPO X BLACK** can influence blood sugar levels in diabetic patients; monitor closely. Dose adjustments to antidiabetic medication might be necessary.
- USN PHEDRACUT LIPO X BLACK** 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 LIPO X BLACK** 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 medicine.
- USN PHEDRACUT LIPO X BLACK** 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 LIPO X BLACK** might exacerbate renal dysfunction.
- Do not exceed the daily recommended dose.

INTERACTIONS:

- Anticoagulant/antiplatelet medicine: USN PHEDRACUT LIPO X BLACK** 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 LIPO X BLACK** could lower the effect of anticonvulsant medicine due to its caffeine content. Taking caffeine in combination with one of the following medicine 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 LIPO X BLACK** 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.
- Calcium channel blockers & nitrates:** The use of **USN PHEDRACUT LIPO X BLACK** with calcium channel blockers (such as verapamil, nifedipine and diltiazem) as well as nitrates such as nitroglycerin might cause additive coronary vasodilatory effects.
- Ephedrine and other stimulants:** The use of **USN PHEDRACUT LIPO X BLACK** 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 LIPO X BLACK** 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 LIPO X BLACK** with MAOIs. MAOIs include phenelzine, tranylcypromine and others.
- Levothyroxine:** The use of **USN PHEDRACUT LIPO X BLACK** 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 LIPO X BLACK**.
- 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 LIPO X BLACK**.
- 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 BLACK**.
- 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 BLACK**.

HUMAN REPRODUCTION:

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

DOSAGE AND DIRECTIONS FOR USE:

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 X BLACK** is not recommended after 4 pm. Take **USN PHEDRACUT LIPO X BLACK** for 5 consecutive days of the week and discontinue use for 2 days before continuing again.

Start with 1 capsule to assess tolerance and increase dosage to a maximum of 2 capsules (full dosage) as tolerated (maximum of 4 capsules per day).

Do not exceed the recommended daily dosage.

SIDE EFFECTS:

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

- 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* – Anxiety, agitation, mood changes.
- Nervous system disorders:** *Frequency unknown* – Dizziness, insomnia, headache, 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, 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:

Black gelatine capsules containing light brown powder with white and dark speckles.

PRESENTATION:

Black HDPE plastic container with a black USN lid, containing 40 or 80 capsules.

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:


June 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.

PHE075-076/PI-PIL/B

| | |
|---|--|
| JOB: SAHC_LIPO X BLACK | SIZE: 280mm x 396mm |
| STOCK: Foil Substrate: <input checked="" type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Other: <input type="checkbox"/> | |
| COLOURS:  | FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Diecut <input type="checkbox"/> Embossing |

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
Not scheduled.

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

USN

USN PHEDRACUT LIPO X BLACK

(capsules)

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

USN PHEDRACUT LIPO X BLACK is available without a doctor's prescription. Nevertheless, you still need to use USN PHEDRACUT LIPO X BLACK carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share USN PHEDRACUT LIPO X BLACK with any other person.
- Ask your pharmacist if you need more information or advice.

1. WHAT USN PHEDRACUT LIPO X BLACK CONTAINS:

| Active ingredients: | Per Capsule | Per Dose | *%NRV |
|---|-----------------|------------------|-------|
| Sinetrol® Xpur (20 % Naringin) | 225 mg | 450 mg | |
| Total Caffeine (from Caffeine Anhydrous & Sinetrol® Xpur) | 100 mg | 200 mg | |
| <i>Coleus forskohlii</i> extract (root; extract standardised to Forskolin 1 %) | 50 mg | 100 mg | |
| L-Theanine | 50 mg | 100 mg | |
| Dynamine™ (40 % Methyliberine) | 31,3 mg | 62.5 mg | |
| <i>Aframomum melegueta</i> (Grains of Paradise) extract [seed; 10:1 extract] | 25 mg | 50 mg | |
| Theacrine 99 % | 10 mg | 20 mg | |
| Chromium picolinate providing Chromium (elemental) | 417 µg 50 µg | 834 µg 100 µg | 286 % |

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

Other ingredients: Bovine gelatine capsules, magnesium stearate, silica (Aerosil®).

Sugar Free

2. WHAT USN PHEDRACUT LIPO X BLACK IS USED FOR:

USN PHEDRACUT LIPO X BLACK is indicated as a thermogenic agent that provides added energy as an aid to a weight management programme combined with a balanced, energy-restricted diet and regular exercise.

3. BEFORE YOU TAKE USN PHEDRACUT LIPO X BLACK:

Do not take USN PHEDRACUT LIPO X BLACK:

- If you are hypersensitive (allergic) to any of the active or inactive ingredients (see WHAT USN PHEDRACUT LIPO X BLACK CONTAINS).
- 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 LIPO X BLACK:

- 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 LIPO X BLACK might interfere with surgical procedures by increasing heart rate and blood pressure.
- If you have diabetes. USN PHEDRACUT LIPO X BLACK can influence blood sugar levels. Dose adjustments to antidiabetic medicine might be necessary. Monitor closely.
- If you have a bleeding disorder. USN PHEDRACUT LIPO X BLACK 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 LIPO X BLACK 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 LIPO X BLACK can temporarily increase intraocular pressure due to the caffeine content.
- If you have a kidney disease, USN PHEDRACUT LIPO X BLACK might worsen kidney dysfunction. Use with caution.
- Do not exceed the daily recommended dose.

Taking USN PHEDRACUT LIPO X BLACK with food and drink:

- USN PHEDRACUT LIPO X BLACK should be taken 30 minutes before meals or snacks (preferably before breakfast and lunch).

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 LIPO X BLACK will affect your ability to drive a vehicle or operate machinery requiring your attention.

Taking other medicines with USN PHEDRACUT LIPO X BLACK:

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 LIPO X BLACK with your doctor or pharmacist first:

- Anticoagulant/antiplatelet medicine (such as aspirin, clopidogrel, heparin, indomethacin and warfarin), as USN PHEDRACUT LIPO X BLACK can inhibit platelet aggregation and might increase the risk of bleeding when used with these medicine.
- Anticonvulsant medicine (such as carbamazepine, ethosuximide, felbamate, phenytoin and valproate), as the caffeine in USN PHEDRACUT LIPO X BLACK can lower the effect of these medicines and increase the risk of seizures (fits).
- Antidiabetic medicine (such as glimepiride, insulin, metformin, etc.). Use of these medicines with USN PHEDRACUT LIPO X BLACK might interfere with blood glucose control and increase the risk of low blood sugar.
- Calcium channel blockers (such as verapamil, nifedipine and diltiazem) and nitrates (such as nitroglycerin), as use of these medicines might cause additive bloodvessel vasodilatory effects when used with USN PHEDRACUT LIPO X BLACK.
- Ephedrine and other stimulants (such as pseudoephedrine, phenylpropanolamine, etc.). These stimulants can increase the risk of stimulatory adverse effects when used with USN PHEDRACUT LIPO X BLACK. 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 LIPO X BLACK 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 LIPO X BLACK.
- 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 LIPO X BLACK.
- 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 LIPO X BLACK.
- 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 LIPO X BLACK.

4. HOW TO TAKE USN PHEDRACUT LIPO X BLACK:

Do not share medicines prescribed for you with any other person. Always take USN PHEDRACUT LIPO X BLACK exactly as directed. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

- 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 X BLACK is not recommended after 4 pm. Take USN PHEDRACUT LIPO X BLACK for 5 consecutive days of the week and discontinue use for 2 days before continuing again.

Start with 1 capsule to assess tolerance and increase dosage to a maximum of 2 capsules (full dosage) as tolerated (maximum of 4 capsules per day).

Do not exceed the recommended daily dosage.

If you take more USN PHEDRACUT LIPO X BLACK 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 LIPO X BLACK:

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 LIPO X BLACK can have side effects.
- Not all side effects reported for USN PHEDRACUT LIPO X BLACK 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, discontinue taking USN PHEDRACUT LIPO X BLACK 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 LIPO X BLACK. 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*.
- Abdominal cramps, gastric irritation.
- Abdominal bloating, flatulence (gas), constipation.
- 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 LIPO X BLACK:

- 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 LIPO X BLACK 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 LIPO X BLACK:

Black HDPE plastic container with a black USN lid, containing 40 or 80 capsules.

8. IDENTIFICATION OF USN PHEDRACUT LIPO X BLACK:

Black gelatine 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 Exit 54
0157
Tel: 0861 111 876

11. DATE OF PUBLICATION:

June 2019.

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.



PASIENTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS:

Nie geskeduleer nie.

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM:

USN

USN PHEDRACUT LIPO X BLACK

(kapsules)

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

USN PHEDRACUT LIPO X BLACK is beskikbaar sonder 'n dokter se voorskrif. Nietemin moet u steeds USN PHEDRACUT LIPO X BLACK versigtig gebruik om die beste resultate te verkry.

- Bewaar hierdie pamflet. U mag dit dalk weer moet lees.
- Moenie USN PHEDRACUT LIPO X BLACK met enige ander persoon deel nie.
- Vra u apteker indien u verdere inligting of advies benodig.

1. WAT USN PHEDRACUT LIPO X BLACK BEVAT:

| Aktiewe Bestanddele: | Per Kapsule | Per Dosering | *%NWV |
|--|-----------------|------------------|-------|
| Sinetrol® Xpur (20 % Naringin) | 225 mg | 450 mg | |
| Totale Kafeien (van Anhidriese Kafeien & Sinetrol® Xpur) | 100 mg | 200 mg | |
| <i>Coleus forskohlii</i> ekstrak [wortel; ekstrak gestandaardiseer tot Forskolin 1 %] | 50 mg | 100 mg | |
| L-Teaïen | 50 mg | 100 mg | |
| Dynamine™ (40 % Metiliberien) | 31,3 mg | 62.5 mg | |
| <i>Aframomum melegueta</i> (Grains of Paradise) ekstrak [saad; 10:1 ekstrak] | 25 mg | 50 mg | |
| Teakrien 99 % | 10 mg | 20 mg | |
| Chroompikolinaat verskaf Chroom (elementeel) | 417 µg 50 µg | 834 µg 100 µg | 286 % |

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

Ander bestanddele: Beesgelatienkapsules, magnesiumstearaat, silika (Aerosil®).

Suikervry

2. WAARVOOR USN PHEDRACUT LIPO X BLACK GEBRUIK WORD:

USN PHEDRACUT LIPO X BLACK word aangedui as 'n termogeniese middel wat aanvullende energie verskaf as 'n hulpmiddel in 'n gewigsbeheerprogram wat 'n gebalanseerde, energiebeperkte dieet en gereelde oefening insluit.

3. VOOR U USN PHEDRACUT LIPO X BLACK NEEM:

Moenie USN PHEDRACUT LIPO X BLACK neem:

- Indien u hipersensitief (allergies) is vir enige van die aktiewe of onaktiewe bestanddele (sien WAT USN PHEDRACUT LIPO X BLACK BEVAT).
- 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 LIPO X BLACK:

- Indien u aan hoë bloeddruk ly. Kafeien kan bloeddruk tydelik verhoog.
- Indien u aan enige hartaestoestand ly. Kafeien, veral wanneer dit in hoë dosisse geneem word, kan lei tot onreëlmattie hartklop in individue wat sensitief is vir kafeien.
- Indien u binne twee weke elektiewe chirurgie ondergaan. Die stimulanteffek van USN PHEDRACUT LIPO X BLACK mag innem met chirurgiese prosedures deur hartklop en bloeddruk te verhoog.
- Indien u 'n diabeet is, kan USN PHEDRACUT LIPO X BLACK bloedsuikervlakke beïnvloed. Dosisaanpassings ten opsigte van antidiabetiese medisyne mag nodig wees. Monitor noukeurig.
- Indien u aan 'n bloedingsiekte ly, mag USN PHEDRACUT LIPO X BLACK die sameklomping van bloedplaatjies inhibeer en sodoen die risiko van kneusing en bloeding verhoog; gebruik met omsigtigheid.
- Indien u aan 'n angsversteuring ly, mag die kafeien die simptome vererger.
- Indien u aan 'n lewersiekte ly, mag USN PHEDRACUT LIPO X BLACK lewerdisfunksie vererger. Gebruik met omsigtigheid.
- Indien u 'n epilepsieslyer is. Kafeien kan die risiko vir konvulsies verhoog en die effektiwiteit van sommige antikonvulsiewe middels verminder.
- Indien u nouhoekgloukoom het, kan USN PHEDRACUT LIPO X BLACK intraokulêre druk tydelik verhoog te wylte aan die kafeïeninoud.
- Indien u aan 'n niersiekte ly, mag USN PHEDRACUT LIPO X BLACK nierdisfunksie vererger. Gebruik met omsigtigheid.
- Moet nie die voorgeskrewe daaglikse dosis oorskry nie.

Neem van USN PHEDRACUT LIPO X BLACK met voedsel en drank:

- USN PHEDRACUT LIPO X BLACK moet 30 minute voor maaltye of versnaperings (verkiieslik voor ontbyt en middagete) geneem word.

Swangerskap en Borsvoeding:

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

Bestuur en gebruik van masjinerie:

Dit is onwaarskynlik dat USN PHEDRACUT LIPO X BLACK 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 LIPO X BLACK:

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 LIPO X BLACK met u dokter of apteker.

- Anti-stolmiddels/antiplaatjemedisyne (soos aspirien, klopidogrel, heparien, indometasien en warfarin), aangesien USN PHEDRACUT LIPO X BLACK die sameklomping 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, fenitoin en valproaat), aangesien die kafeien in USN PHEDRACUT LIPO X BLACK die effek van hierdie medisyne kan verminder en die risiko van konvulsies verhoog.
- Antidiabetiese medisyne (soos glimepiried, insulien, metformien, ens.). Gebruik van hierdie medisyne saam met USN PHEDRACUT LIPO X BLACK mag innem met bloedglukosebeheer en die risiko van lae bloedsuiker verhoog.
- Kalsiumkanaalblokkers (soos verapamil, nifedipien en diltiazem) en nitrate (soos nitrogliiserien), aangesien gebruik van hierdie medisyne additiese vasodilatatoriese effekte tot gevolg kan hê wanneer saam met USN PHEDRACUT LIPO X BLACK gebruik word.
- Efedrien en ander stimulant (soos pseudo-efedrien, fenilpropanolamien, ens.). Hierdie stimulant kan die risiko van stimulerende nadelige effekte verhoog wanneer saam met USN PHEDRACUT LIPO X BLACK gebruik. Die gebruik van efedrien saam met kafeien mag die risiko verhoog van ernstige lewensbedreigende nadelige effekte soos hoë bloeddruk, hartaanval, beroerte, konvulsies en sterfte. Vermy saamlopende gebruik.
- Monoamienoksidaseremmers (MAOIs) (soos fenelisien, trianielsipromien en ander), aangesien hierdie medisyne gebruik saam met kafeien bloeddruk mag verhoog en 'n hipertensiewe krisis mag veroorsaak. Vermy saamlopende gebruik.
- Levtiroksien, aangesien die chroom in USN PHEDRACUT LIPO X BLACK kan bind met die levtiroksien in die dermkanaal en 'n verlaging in die levtiroksien serumvlakke kan veroorsaak. Neem levtiroksien ten minste 30 minute voor of 3-4 ure na die neem van USN PHEDRACUT LIPO X BLACK.
- Kruie en aanvullings met stimulerende effekte (bittermeoenaanvullings sowel as ander kafeïenbevattende kruie en aanvullings soos koffie, guarana, maté, ens.) kan die risiko van hoë bloeddruk en kardiovaskulêre nadelige effekte verhoog wanneer saam met USN PHEDRACUT LIPO X BLACK gebruik.
- Kruie en aanvullings met anti-stol/antiplaatjie eienskappe (soos knoffel, gemmer, borrie, ens.) kan die risiko van kneusing en bloeding verhoog indien saam met USN PHEDRACUT LIPO X BLACK gebruik word.
- Kruie en aanvullings met hipogluksemiese potensiaal (soos fenegriek, knoffel, Panax ginseng, ens.), aangesien hierdie aanvullings die risiko van lae bloedsuiker kan verhoog indien saam met USN PHEDRACUT LIPO X BLACK gebruik word.

4. HOE OM USN PHEDRACUT LIPO X BLACK TE NEEM:

Moenie medikasie wat vir u voorskryf is met enige ander persoon deel nie. Neem altyd USN PHEDRACUT LIPO X BLACK presies soos voorskryf. Raadpleeg u dokter of apteker indien u onseker is.

Die gewone dosis is:

- Volwassenes:** Neem 2 kapsules tweekeer daaglik, 30 minute voor maaltye/versnaperings (verkiieslik voor ontbyt en middagete). Indien u vroeg-oggend oefen, neem 2 kapsules voor die oefensessie, en eet dan direk na die oefensessie ontbyt. USN PHEDRACUT LIPO X BLACK word nie na 4 nm aanbeveel nie. Neem USN PHEDRACUT LIPO X BLACK vir 5 opeenvolgende dae van die week, gevolg deur 'n 2-dag onderbreking, voordat die siklus weer voortgesit word.

Begin met 1 kapsule om toleransievak te bepaal en verhoog dosering tot 'n maksimum van 2 kapsules (volle dosering) soos verdra (maksimum van 4 kapsules per dag).

Moenie die aanbevole daaglikse dosering oorskry nie.

Indien u meer USN PHEDRACUT LIPO X BLACK 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 giftebeheersentrum.

Indien u vergeet om USN PHEDRACUT LIPO X BLACK te neem:

Neem die dosis wat u oorgeslaan het sodra u onthou. Indien dit amper tyd is vir die volgende dosis, moenie die vergeete dosis neem nie, maar neem die volgende dosis die normale tyd.

Moenie 'n dubbele dosis neem om op te maak vir die vergeete individuele dosis nie.

5. MOONTLIKE NEWE-EFFEKTE:

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

| | |
|---|---|
| JOB: SAHC_LIPO X BLACK | SIZE: 280mm x 396mm |
| STOCK: Foil Substrate: <input checked="" type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input 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"/> Dinking <input type="checkbox"/> Embossing |

PHE075-076/PI-PIL/B