

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS:

Not scheduled.

### PROPRIETARY NAME AND DOSAGE FORM:



# USN KETO FAT BURN

36294 P15

(capsules)

### COMPOSITION:

#### Active Ingredients:

	Per Capsule	Per Dose	*%NRV
Caffeine Anhydrous	100 mg	200 mg	
Potassium (as Potassium Chloride)	100 mg	200 mg	
TeaCrine® 97 %	20 mg	40 mg	
Thermozine™ [Aframomum melegueta (Grains of Paradise) (seed; 10:1 extract)]	20 mg	40 mg	
Chromium (from Chromium Picolinate)	50 µg	100 µg	286 %

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

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

Sugar Free

### CATEGORY AND CLASS:

D 33.7 Combination Product

### PHARMACOLOGICAL ACTION:

**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.

**Potassium:** Potassium is the most abundant intracellular electrolyte found in the body. Potassium contributes to normal muscle function and plays a factor in the maintenance of good health.

**TeaCrine® 97 %:** TeaCrine® is pure 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.

**Grains of Paradise extract:** Grains of Paradise, is a standardised extract from seeds of the *Aframomum melegueta* plant. 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 KETO FAT BURN** is indicated as a thermogenic agent that provides added energy & mental focus as an aid to a weight management programme combined with a ketogenic diet and regular exercise.

### CONTRAINDICATIONS:

This product is contraindicated for individuals that are hypersensitive (allergic) to any of the listed ingredients. This includes an allergy to ginger, as Grains of Paradise is a member of the *Zingiberaceae* (ginger) family.

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 and sodium might 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 KETO FAT BURN** might interfere with surgical procedures by increasing heart rate and blood pressure.
- Use with caution in patients with diabetes. **USN KETO FAT BURN** can influence blood sugar levels in diabetic patients; monitor closely. Dose adjustments to antidiabetic medication might be necessary.
- USN KETO FAT BURN** 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 KETO FAT BURN** 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 KETO FAT BURN** 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 KETO FAT BURN** might exacerbate renal dysfunction (who may also be on a potassium-restricted diet, due to the risk of potassium accumulation leading to hyperkalaemia). Closely monitor serum electrolytes when potassium is used by people with renal dysfunction.
- Do not exceed the daily recommended dose.

### INTERACTIONS:

- Anticoagulant/antiplatelet medicine:** **USN KETO FAT BURN** 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 KETO FAT BURN** 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 KETO FAT BURN** 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.
- Ephedrine and other stimulants:** The use of **USN KETO FAT BURN** 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 KETO FAT BURN** 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 KETO FAT BURN** with MAOIs. MAOIs include phenelzine, tranylcypromine and others.
- Levothyroxine:** The use of **USN KETO FAT BURN** 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 KETO FAT BURN**.
- Potassium-sparing diuretics:** Potassium-sparing diuretics are diuretics that result in increased urine production and increasing serum levels of potassium. Concurrent use can result in increased potassium levels and side-effects. Some potassium-sparing diuretics include amiloride, spironolactone and others.
- 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 KETO FAT BURN**.
- 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 KETO FAT BURN**.
- 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 KETO FAT BURN**.

### HUMAN REPRODUCTION:

Safety has not been established for use during pregnancy and lactation. Do not use **USN KETO FAT BURN** if you are pregnant or lactating.

### DOSAGE AND DIRECTIONS FOR USE:

**Adults:** As a dietary supplement, take 1 to 2 capsules 1-2 times daily. Take first dosage on an empty stomach in the morning (ideally 30 minutes before exercise) and a second dosage 30 minutes prior to a light lunch. 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). Not suitable for use after 4 pm.

Take **USN KETO FAT BURN** 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 **USN KETO FAT BURN**:

- 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:

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

### PRESENTATION:

White HDPE plastic container with a white USN lid, containing 90 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:

October 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.

<b>JOB:</b> USNSAK_KetoFatBurn_90s	<b>SIZE:</b> 300mm x 385mm
<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> <input checked="" type="checkbox"/> K <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<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"/> Doming <input type="checkbox"/> Embossing

