

SCHEDULING STATUS Not scheduled
PROPRIETARY NAME AND DOSAGE FORM:

USN®

34717 P/B

USN PHEDRACUT BURN XT

(capsule)

COMPOSITION:

Active ingredients:	Per Capsule	Per Dose	%NRV
Total Caffeine (from Caffeine Anhydrous, Green Coffee Bean extract & Green Tea extract)	66,7 mg	200 mg	
Green Coffee Bean (<i>Coffea robusta</i>) extract (45 % Chlorogenic Acid)	66,7 mg	200 mg	
Green Tea (<i>Camellia sinensis</i>) extract (45 % EGCG)	66,7 mg	200 mg	
L-Tyrosine	66,7 mg	200 mg	
Zinc (as Zinc Lactate 3-Hydrate)	2,4 mg	7,2 mg	65 %
BioPerine® (Black Pepper) (<i>Piper nigrum</i> L.) extract (standardised to 95 % Piperine)	1,7 mg	5 mg	
Pantothenic Acid (as Calcium-D-Pantothenate)	0,3 mg	1 mg	20 %
Chromium (from Chromium Picolinate)	16,7 µg	50 µg	143 %
Vitamin B12 (as Cyanocobalamin)	0,8 µg	2,4 µg	100 %

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

Other ingredients: Bovine gelatine capsules, magnesium stearate, silicon dioxide, starch.

Sugar Free

CATEGORY AND CLASS

D 33.7 Combination Product

PHARMACOLOGICAL ACTION

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 Coffee Bean extract contains high concentrations of chlorogenic acids that are known to have health benefits and to influence glucose and fat metabolism, influencing postprandial blood sugar concentration, glucose tolerance, serum lipid concentration and glucose absorption from the intestine. There have been some recent articles indicating that chlorogenic acid and its metabolite, caffeic acid, inhibit amylase at mM concentrations *in vitro* which, if it occurred in the gastrointestinal tract *in vivo*, would inhibit sugar absorption from starch consumption and thus decrease caloric input. The study showed that coffee (decaffeinated or caffeinated) when compared with a control drink, significantly attenuated the postprandial release of Gastric Intestinal Peptide (GIP) in the proximal part of the small intestine. As the quantity of glucose absorbed at the intestinal barrier determines the magnitude of the GIP response, these results suggest that coffee decreases the absorption of glucose from the small intestine. This relative deprivation of glucose could possibly explain the reduction in Body Mass Index as well as fat content seen. Another group has clearly demonstrated that chlorogenic acid may in fact have an antagonistic effect on human glucose transport. Extracts of green coffee beans inhibited pancreatic lipase *in vitro* with a 50 % inhibitory concentration of 43 µM polyphenols. In support of this result, caffeinated but not decaffeinated coffee supplementation in humans, produced a decrease in lipoprotein lipase.

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.

L-Tyrosine: L-Tyrosine is a source of an amino acid involved in muscle protein synthesis. It also helps to decrease cognitive fatigue due to physically stressful situations.

Zinc: Zinc helps to metabolise carbohydrates, fats and proteins and assists with connective tissue formation.

BioPerine® is a patented standardised extract from black pepper containing 95 % piperine (a bioavailability enhancer for nutrients). Used in combination with other ingredients it may enhance the uptake and utilisation of the natural actives increasing the bioavailability of supplemented nutrients through increased absorption. As a thermotrient, BioPerine® would potentially improve the process of nutrient absorption by enhancing thermogenesis. Most of the food or thermotrient-induced thermogenesis is facilitated by beta receptors, which include a compound known as cyclic adenosine 3', 5' monophosphate (cAMP). The role of cAMP as a "second messenger" to the hormonal and enzymatic actions in the body is well recognized. Piperine has been found in independent studies to stimulate the release of catecholamines, thermogenic hormones whose action is made possible by the presence of cAMP. Other mechanisms by which piperine stimulate nutrient absorption have also been discussed in literature. These include increased micelle formation, stimulation of active transport of amino acids (gamma-glutamyl transpeptidase), and epithelial cell wall modification due to the affinity of piperine towards fats and fatty substances.

Pantothenic Acid (as Calcium-D-Pantothenate): Pantothenic acid helps to metabolise carbohydrates, fats and proteins.

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.

Vitamin B12: Vitamin B12 helps to metabolise carbohydrates, fats and proteins and contributes to normal energy-yielding metabolism.

INDICATION

PHEDRACUT BURN XT is indicated as an aid to a weight management programme that includes a balanced, energy-restricted diet and regular exercise.

CONTRAINDICATIONS

Avoid with known allergy or hypersensitivity to tea, any of its constituents including caffeine or tannins, known allergy/hypersensitivity to black pepper (*Piper nigrum*), its constituents, or members of the *Piperaceae* family; or known allergy/hypersensitivity to any of the other ingredients.

Piper nigrum have been shown to produce anti-thrombin, and *in vitro* reports further suggest that piperine inhibits platelet aggregation. This product is contra-indicated for use in combination with anti-coagulant or anti-platelet medications such as Warfarin.

Do not use if you are pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS

Not recommended for use in children under the age of 18 years.

Do not use if sensitive to caffeine.

Diabetics/hypoglycaemic individuals should take note that this product may reduce blood sugar levels - diabetics may need to reduce medication dosages. Please discuss with your healthcare professional before taking this medicine.

Use cautiously in patients with hypertension, due to possible hypertensive effects.

Use cautiously in individuals with or at risk of cardiovascular disease (other than atrial fibrillation) or users of tobacco or nicotine, due to reports of atrial fibrillation associated with the EGCG component and heart palpitations or arrhythmias associated with caffeine.

Use with caution in patients with renal disease; chromium might exacerbate renal dysfunction.

Consult a health care practitioner prior to use if you are following a low protein diet.

If nausea, headaches, heartburn, stomach pain, or depression is a result, lower dosage or discontinue use if the symptoms persist for more than a week.

Remember that an adequate state of hydration must be maintained when using this product. Have at least 8-12 glasses of water per day.

Please discuss with your healthcare professional before taking this medicine.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine.

Use cautiously in patients with diabetes (on medication), as **PHEDRACUT BURN XT** might interfere with blood glucose control.

The use of alcohol can increase caffeine serum concentrations and the risk of caffeine adverse effects.

It is not recommended to use with antiplatelet agents like aspirin and/or ephedrine.

PREGNANCY AND LACTATION

Do not take this medicine during pregnancy or lactation.

DOSAGE AND DIRECTIONS FOR USE

Adults: Take 3 capsules twice daily, 30 minutes prior to meals (preferably breakfast and lunch). If training early morning, take 3 capsules prior to workout, and follow with breakfast directly after training. Due to high stimulant content **PHEDRACUT BURN XT** is not recommended after 4 pm.

Take **PHEDRACUT BURN XT** for 5 consecutive days of the week and stop use for 2 days before continuing again (2 off days).

Do not exceed the daily recommended dose. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Do not share medicines prescribed for you with any other person.

SIDE-EFFECTS

Gastrointestinal disorders: Abdominal discomfort, flatulence, diarrhoea, constipation, nausea, vomiting, heartburn, gastralgia, dyspepsia.

Immune system disorders: Hypersensitivity and/or allergic reactions.

Endocrine disorders: Hypoglycaemia.

Nervous system disorders: Headache, dizziness, agitation, insomnia, depression.

Renal disorders: Diuretics, renal disease.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

None known. Treatment is symptomatic and supportive.

IDENTIFICATION

White capsule, containing a light brown powder. "USN XT" is printed in yellow on the capsule.

PRESENTATION

White plastic container with 30/60/120 capsules or a white foil/plastic bag containing 21 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

July 2014

COMPLEMENTARY MEDICINE

Discipline: Combination Product - Western Herbal Medicine & Health Supplement.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SIZE: 250 x 195 **FINISHING:** EMOSS SPOT DOMING: FOIL: HOLOGRAPHIC FOIL: **CONTENT:** **STOCK:** PAPER: SUBSTRATE: OTHER:

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PHE064-COM265/P/B

SKEDULERINGSSTATUS Nie geskeduleer
HANDELSNAAM EN DOSEERVORM:



USN PHEDRACUT BURN XT

(kapsule)

SAMESTELLING:

Aktiewe Bestanddele:	Per Kapsule	Per Dosering	%NWW
Totale Kafieën (van Anhidriese Kafieën, Groenkoffieboom-ekstrak & Groentee-ekstrak)	66,7 mg	200 mg	
Groenkoffieboom (<i>Coffea robusta</i>) ekstrak (45 % Chlorogeensuur)	66,7 mg	200 mg	
Groentee-ekstrak (<i>Camellia sinensis</i>) (45 % EGCG)	66,7 mg	200 mg	
L-Tirosien	66,7 mg	200 mg	
Sink (as Sinklaktaat 3-Hidraat)	2,4 mg	7,2 mg	65 %
BioPerine® (Swartpeper) (<i>Piper nigrum</i> L.) ekstrak (gestandaardiseer tot 95 % Piperien)	1,7 mg	5 mg	
Pantoteensuur (as Kalsium-D-Pantoteensuur)	0,3 mg	1 mg	20 %
Chroom (van Chroomkoliniaat)	16,7 µg	50 µg	143 %
Vitamiën B12 (as Sianokobalamien)	0,8 µg	2,4 µg	100 %

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

Ander bestanddele: Beesglatienkapsules, magnesiumstearaat, silikondioksied, stysel.

Suikervry

KATEGORIE EN KLAS

D 33.7 Kombinasie Produk

FARMAKOLOGIESE AKSIE

Kafieën: Kafieën verhoog rustende energie-besteding of rustende metaboliese tempo, asook sellulêre termogenese. Die termogeniese effek van kafieën kan wees as gevolg van vasokonstriksie en verhoging in vasikulêre gladdepiertonus. Kafieën veroorsaak ook 'n verhoging in nie-oksidasiewe vetsuur omskakeling en lipied-oksidasie. Die effek van kafieën op energie besteding en lipied metabolisme word bemiddel deur beide simpatisse en nie-simpatisse meganismes.

Groenkoffieboom-ekstrak bevat hoë konsentrasies chlorogeensuur, wat bekend is vir die gesondheidsvoordele daarvan en dat dit glukose- en vetmetabolisme, bloedsuikerkonsentrasie na maaltye, glukosetoleransie, serumlipiedkonsentrasie en glukose-opname uit die dunderm beïnvloed. Daar is 'n paar onlangse artikels wat daarop dui dat chlorogeensuur en die metaboliet daarvan, koffiesuur, amilase *in vitro* rem by mM-konsentrasies, wat, indien dit *in vivo* in die spysverteringskanaal plaasgevind het, suikeropname met styselvertering sou rem en aldus energie-inname verminder. Die studie het getoon dat koffie (kafieënvry of met kafieën), in vergelyking met 'n kontrole drankie, die vrystelling van Gastro-intestinale Peptiede (GIP) na maaltye in die proksimale deel van die dunderm beduidend verminder. Aangesien die hoeveelhede glukose wat deur die dermwand geabsorbeer word die omvang van die GIP-reaksie bepaal, dui hierdie resultate daarop dat koffie die opname van glukose uit die dunderm verminder.

Hierdie relatiewe weerhouding van glukose kan moontlik die waarnemings van verlaagde LMI en vetinhouid verduidelik. Daar is met nog 'n groep duidelik aangetoon dat chlorogeensuur in werklikheid 'n antagonisiese effek op menslike glukosetransport kan hê. Ekstrakte van groenkoffiebone het pankreatiese lipase *in vitro* gerem, met 'n 50 % inhibitiese konsentrasie van 43 µM polifenole. Ter ondersteuning van hierdie uitslag, het koffie met kafieën, maar nie kafieënvrye koffie-aanvullings nie, by die mens 'n afname in lipoproteïen-lipase opgelewer.

Groentee-ekstrak: Die polifenole in groentee het 'n antioksidant werking. In menslike navorsing het groentee-polifenole spierthouvermoë verbeter en 'n verhoging in plasma kreatienkinase-aktiwiteit verhoed wat gesien is in die plasebo groep na oefening. Studies wys dat groentee bloedsuikervlakke mag moduleren en vlakke van insulien en insulienweerstandigheid beïnvloed. Aanvulling met EGCG, een van die katesjien, het volhouding met 'n dieet by oorgewig, maar andersins gesonde, profepersone verbeter.

L-Tirosien: L-Tirosien is 'n bron van 'n aminosuur betrokke in spierproteïensintese. Dit help ook om kognitiewe uitputting te verminder as gevolg van fisies stresvolle situasies.

Sink: Sink help met die metabolisering van koolhidrate, vette en proteïene en help met bindweefsel vorming.

BioPerine® is 'n gepatenteerde, gestandaardiseerde ekstrak vanuit swartpeper met 95 % piperien ('n verhoging in bio beskikbaarheid vir voedingstowwe). Wanneer dit in kombinasie met ander bestanddele gebruik word, kan dit die opname en benutting van die natuurlike aktiewe stowwe verbeter en so die bio beskikbaarheid van aangevulde voedingstowwe deur beter absorpsie verbeter. As 'n hitteproduserende voedingsstof kan BioPerine® potensieel die absorpsieproses van voedingstowwe verbeter deur verbeterende hitte-opwekking. Die grootste gedeelte van die hitte-opwekking afkomstig van kos of hitteproduserende voedingsstowwe, word deur beta-reseptore gefasiliteer; dit sluit 'n verbinding in wat bekend staan as sikliese adenosien 3', 5' monofosfaat (sAMF). Die rol van die sAMF as 'n "tweede boodskap" aan die hormonale en ensiematiese werkings in die liggaam word wyd erken. Daar is 'n onafhanklike navorsingsstudie bevind dat piperien die vrystelling van katesjolamiene, hitte-opwekkende hormone, waarvan die werking deur die teenwoordigheid van sAMF moontlik gemaak word, stimuleer. Ander meganismes waardeur piperien die absorpsie van voedingstowwe stimuleer is ook in publikasies bespreek. Dit sluit in verhoogde miselvorming, stimulasie van aktiewe transport van aminosure (gammaglutamiel transpeptidase) en verandering van die eptiteelselwand as gevolg van die affiniteit van piperien vir vette en vetterige stowwe.

Pantoteensuur (as Kalsium-D-Pantoteensuur): Pantoteensuur help met die metabolisering van koolhidrate, vette en proteïene.

Chroom (van Chroomkoliniaat): Dra by tot die handhawing van normale bloedglukose vlakke. Chroom se meganisme om insulienweerstandigheid te verlaag is as gevolg van 'n verbeterde eerste fase sekresie van insulien of gefasiliteerde post-reseptor insulien sensitiwiteit as 'n manier om die aksie van insulien te potensieer.

Dus, om chroom te neem voor 'n hoë koolhidraat ete blyk postprandiale hiperglukemie te verminder. Chroomkoliniaat mag ook vet drange en honger verminder deur die brein se hongereceptor te affekteer. Dit is as gevolg van die feit dat chroom insulien-glukosereptore in die brein mag sensitief maak, wat eeluisonderdrukking, stimulering van termogenese en afregulering van insulien sekresie tot gevolg het.

Vitamiën B12: Vitamiën B12 help met die metabolisering van koolhidrate, vette en proteïene asook normale energie-wekkende metabolisme.

INDIKASIES

PHEDRACUT BURN XT word aangedui as 'n hulpmiddel in 'n gewigsbeheerprogram wat 'n gebalanseerde, energiebeperkte dieet en gereelde oefening insluit.

KONTRA-INDIKASIES

Vermyn met bekende allergie of hipersensitiwiteit vir tee, enige van sy bestanddele, insluitende kafieën of tannien, bekende allergie / hipersensitiwiteit vir swartpeper (*Piper nigrum*), sy bestanddele, of lede van die familie *Piperaceae*; of bekende allergie / hipersensitiwiteit vir enige van die ander bestanddele.

Piper nigrum het getoon dat dit anti-trombin produseer, en *in vitro* verslae dui verder daarop dat piperien plaatjeklompig rem. Hierdie produk word teenaangedui vir gebruik in kombinasie met antistollings- of antiplaatjemiddels soos warfarin.

Vermyn gebruik indien jy swanger is of jou baba borsvoed.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

Nie aanbeveel vir gebruik by kinders jonger as 18 jaar nie.

Moenie gebruik as jy sensitief is vir kafieën nie.

Diabete/hipoglukemiese individue moet daarop let dat hierdie produk bloedsuikervlakke kan verlaag - diabete sal dalk hul medisyne dosisse moet verminder. Bespreek die gebruik van hierdie medikasie met u geneesheer voor gebruik.

Gebruik met versigtigheid by pasiënte met hipertensie, as gevolg van moontlike hipertensiewe effekte.

Gebruik versigtig by individue wat 'n risiko loop vir, of reeds kardiovaskulêre siekte (anders as atriale fibrillasie) het, of gebruikers van tabak of nikotien, aangesien daar berigte was oor atriale fibrillasie geassosieer met die EGCG komponent en hartklompings of disritmie wat verband hou met kafieën.

Gebruik met omsigtigheid in pasiënte met niersiektes; chroom mag nierdistfunksie vererger.

Raadpleeg 'n gesondheidsorgeskundige voor gebruik indien u 'n lae proteïen dieet moet volg.

Indien naarheid, hoofpyn, sooilbrand, maagpyn of depressie voorkom, verlaag die dosis of staak gebruik indien die simptome vir meer as 'n week voortduur.

Onthou dat 'n voldoende stand van hidrasie volgehou moet word wanneer hierdie produk gebruik word. Neem ten minste 8-12 glase water per dag.

Bespreek asseblief met jou gesondheidspraktisyn voordat jy hierdie medisyne gebruik.

INTERAKSIES

Lig altyd jou professionele gesondheidspraktisyn in indien jy enige ander medisyne neem.

Gebruik versigtig in pasiënte met diabetes (op medikasie), aangesien **PHEDRACUT BURN XT** met bloedglukose-beheer mag inmeng. Die gebruik van alkohol kan kafieën serum konsentrasies en die risiko van kafieën se nadelige gevolge verhoog.

Dit word nie aanbeveel om met anti-plaatjie middels soos aspirien en / of efedrien te gebruik nie.

SWANGERSKAP EN LAKTASIE

Vermyn die gebruik van hierdie produk tydens swangerskap en laktasie.

DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes: Neem 3 kapsules tweemaal per dag, 30 minute voor maaltye (ver kieslik ontyt by middagete). Indien u vroeg-oggend oefen, neem 3 kapsules voor die oefensessie en eet dan direk na die oefensessie ontyt.

Weens die hoë stimulant inhoud van **PHEDRACUT BURN XT** word inname nie na 4 nm aanbeveel nie.

Neem **PHEDRACUT BURN XT** vir 5 opeenvolgende dae van die week, gevolg deur 'n 2-dag onderbreking, voordat die siklus weer begin word (2 dae af).

Moenie die aanbevole daaglikse dosering oorskry nie.

In die geval van oordosering skakel dringend u dokter of apteker. Indien hul nie beskikbaar is nie kontak u naaste hospitaal of gifbeheersentrum.

Moenie medisyne wat vir jou voorgeskryf is met ander mense deel nie.

NEWE-EFFEKTE

Gastro-intestinale versteuring: Buik-ongemak, wonderigheid, diarree, hardlywigheid, naarheid, braking, sooilbrand, gastralgie, dispepsie.

Immuunsisteem versteuring: Hipersensitiwiteit en/of allergiese reaksies.

Endokriene sisteem versteurings: Hipoglukemie.

Neurologiese stelsel versteurings: Hoofpyn, duiseligheid, onrustigheid, slapeloosheid, depressie.

Renale versteurings: Diuresis, niersiekte.

Nie alle nuwe-effekte wat vir hierdie medisyne aangemeld is, word in hierdie inligtingsblad genoem nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy hierdie medisyne neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidspraktisyn.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING

Geen. Behandeling is simptomaties en ondersteunend van aard.

IDENTIFIKASIE

'n Wit kapsule, wat 'n ligte bruin poeier bevat. "USN XT" is in geel gedruk op die kapsule.

AANBIEDING

'n Wit plastiekhouer met 30/60/120 kapsules of 'n wit boelie-/plastieksakkie wat 21 kapsules bevat.

BERGINGSAAWYSINGS

Bêre op 'n koel, droë plek teen of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIONOMMER

Vir toekennings deur die Raad.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

USN (Edms) Bpk

Gebou C, Southdowns Besigheidspark, 2de Vloer,

Karestraat 21, Irene Uitr.54, 0157.

Tel: 0861 111 876

DATUM VAN PUBLIKASIE VAN DIE PROFESSIONELE INLIGTING

Julie 2014

KOMPLEMENTÊRE MEDISYNE

Dissipline: Kombinasie Produk - Westerse Kruiemedyne & Gesondheidsaanvulling.

Hierdie ongeregisteerde medisyne is nie deur die SAHPRA geëvalueer vir sy kwaliteit, veiligheid of beoogde gebruik nie.

SIZE: 250 x 195 FINISHING: EMBOSS SPOT DOMING: FOIL: HOLOGRAPHIC FOIL: CONTENT: STOCK: PAPER: SUBSTRATE: OTHER:

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SIGNATURE: I HEREBY CONFIRM THAT THE ARTWORK IS ACCORDING TO SPECIFICATIONS AND APPROVE ARTWORK TO BE UPLOADED FOR PRINTING.

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