Scheduling status

Category D Medicine.

Proprietary name (and dosage form)

NPL Series Black

HALO BURN

Capsules

Composition

Each dose (4 capsules) provides:		%NRV
DAY		
Chromium Picolinate	36 ug	103 %
Pyridoxine HCI (Vitamin B6)	50 mg	2941 %
Cyanocobalamin (Vitamin B12)	50 ug	2083 %
Sinetrol® XPUR	450 mg	-
Grapefruit (Citrus paradisi, fruit extract)	270 mg	-
Guarana (Paulina Cupana, seed extract)	90 mg	-
Sweet orange (Citrus sinensis, fruit extract)	67.5 mg	-
Blood orange (Citrus sinensis, fruit extract)	22.5 mg	-
Aframomum Melegueta (Grains of paradise, 30 mg of a 10:1 extract providing 300 mg of dried herb equivalent)	300 mg	-
Total caffeine	295 mg	-
Of which: Caffeine anhydrous	285 mg	-
Sinetrol® XPUR	10 mg	-
Taraxacum officinale (Dandelion, root, 50 mg of 4:1 extract providing 200 mg of dried herb equivalent)	200 mg	-
Theobromine (Cocoa extract, standardised to 20% extract)	100 mg	-
Arctostaphylos Uva-ursi (Bear berry powder)	100 ma	_
Bioperine® (Piper nigrum, standardised to 95% black pepper extract)	5 mg	-
Huperzia Serrata (Clubmoss leaf extract standardised to 1% huperzine A)	36 ug	-
NIGHT Choline Bitartrate	000	40 %
	200 mg	40 %
Withania Somnifera (Ashwagandha, root, 20 mg of a 15:1 extract providing 300 mg of dried herb equivalent)	300 mg	-
Valeriana officinalis (Valerian, root, 75 mg of a 4:1 extract providing 300 mg of dried herb equivalent)	300 mg	-
L-Tryptophan	220 mg	-
N-acetyl I-carnitine HCI	200 mg	-
Ocimum tenuiflorum (Holy basil, leaf, 20 mg of a 10:1 extract providing 100 mg of dried herb equivalent)	200 mg	-
Matricaria chamomilla (Chamomile powder)	200 mg	-
L-Theanine	50 mg	-

^{* %}Nutrient Reference Values (NRV's) for individuals 4 years and older (2010)

Other ingredients: gelatine (bovine) capsule, magnesium stearate (E572), glidant (E551). Sugar free.

PHARMACOLOGICAL CLASSIFICATION:

Category D Medicine, 33.7 – Combination product.

PHARMACOLOGICAL ACTION:

Caffeine acts on the central nervous system as a stimulant and has a stimulatory effect on general metabolic function.

Sinetrol is thought to facilitate lipolysis trough the inhibition of phosphodiesterase PDE-4, the enzyme that catalyzes the hydrolysis of cyclic adenosine monophosphate (cAMP). Consequently, higher cAMP levels lead to an increased rate of triglyceride (TG) breakdown.

Grains of paradise contain vanilloid compounds 6-gingerol, 6-paradol, and 6-shogaol and may provide anti-inflammatory effects. In addition, Grains of paradise may potentially improve body fat content, increase energy expenditure through activation of the sympathetic nervous system, brown adipose tissue, and vanilloid receptor 1.

Theanine is the major amino acid found in green tea. It is traditionally used for relaxation and reducing anxiety.

Ashwagandha contains several active constituents including alkaloids, steroidal lactones, and saponins and may have sedative and anti-stress affects by suppressing stress-induced increases of dopamine receptors. L-tryptophan is an essential amino acid. After consumption, L-tryptophan is converted to 5-hydroxytryptophan (5-HTP), and then to serotonin which may elicit a sedative affect.

INDICATIONS:

Halo Burn is indicated as a weight management aid that may facilitate weight management when used with a balanced, kilojoule-controlled eating plan and regular exercise.

CONTRAINDICATIONS:

If you suffer from anxiety or depression consult with your healthcare practitioner before using this product.

Diabetics should use this product under the supervision of their healthcare practitioner and blood glucose levels should be monitored closely. If you suffer from high blood pressure, use this product under the supervision of your healthcare practitioner.

Discontinue use 2 weeks prior to any planned surgical procedure.

INTERACTION:

ANTIDEPRESSANT DRUGS. Theoretically, combining with other antidepressant or other serotonergic drugs might increase the risk of serotonergic side effects, including serotonin syndrome.

MONOAMINE OXIDASE INHIBITORS (MAOIs). Concomitant use might result in increased blood pressure. Avoid taking together with MAOIs

ANTICOAGULANT/ANTIPLATELET DRUGS. There is preliminary evidence of platelet aggregation inhibition. Theoretically, taking along with anticoagulant or antiplatelet

drugs might increase the risk of bruising and bleeding.

ANTIDIABETES DRUGS. Theoretically, concomitant use might cause additive hypoglycaemic effects. Dosing adjustments for insulin or oral hypoglycaemic agents may be necessary.

THYROID HORMONE. There is a concern that this might have additive effects with thyroid hormone medications. Dosing adjustments may be necessary.

ANTIHYPERTENSIVE DRUGS. Concomitant use may potentiate the activity of antihypertensive medications.

HUMAN REPRODUCTION:

Pregnant and breastfeeding women should avoid using this product.

DOSAGE AND DIRECTIONS FOR USE:

Take 4 capsules daily Take 2 capsules (white) 30 minutes before breakfast or morning exercise. Take 2 capsules (black) 30 minutes before bedtime. Do not take Halo Burn (white capsules) within 5 hours of bedtime. Maintain an adequate state of hydration. Do not exceed the recommended dosage.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Discontinue the use of this product where there is sensitivity towards any of the ingredients.

KNOWN SYMPTOMS OF OVERDOSE AND TREATMENT:

Use only as directed.

IDENTIFICATION:

Halo Burn Day: White, size 00 capsules with brown powder. Halo Burn Night: Black, size 00 capsules with brown powder.

PRESENTATION:

Black and white carton with (12) blister packs of 10 capsules (60 white and 60 black).

STORAGE INSTRUCTIONS:

Store at or below 25° C. Protect from light and moisture. Keep out of reach of children.

⁻ Not established

REGISTRATION NUMBER/APPLICATION NUMBER:

This medicine has not been evaluated by the South African Health Products Regulatory Authority. This medicine is not intended to diagnose, treat, cure, or prevent any disease.

NAME AND BUSINESS ADDRESS OF APPLICANT:

Nutritional Performance Labs PO Box 2424, Northriding, Randburg, 2162 011 043 2525 info@npl.za.com www.npl.za.com

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

June 2022

DISCIPLINE OF THE MEDICINE

Combination Western Herbal

REFERENCES

Human Psychopharmacology Clinical and Experimental 2004; 58: 390-401

JAMA 2004: 291: 1231-9

Journal of Nutrition 2002: 132: 55-8.

Journal of Pharmacology and Experimental Therapeutics 2001; 299: 96-104

Leung AY, Foster S: Encyclopedia of Common Natural Ingredients Used in Food, Drugs and Cosmetics; 2nd edition; New York; John Wiley & Sons; 1996

2022 Therapeutic Research Center, Natural Medicines, Online resource. Accessed 06/09/2022.

https://naturalmedicines.therapeuticresearch.com