

NATURAL HEALTH PRODUCT

WORKOUT SUPPLEMENTS

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Notes

- ► Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ► The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.
- Sodium is not permitted as a medicinal ingredient on this monograph due to health concerns associated with chronic supplemental use, namely hypertension, which remains the most common and most important risk factor for cardiovascular disease. However, the use of sodium as a counter-ion in medicinal or non-medicinal ingredients (e.g. sodium salts of minerals) is acceptable where warranted.

Date

December 30, 2022

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Group 1: Proteins

	Source information			
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)
 Alfalfa protein concentrate Medicago sativa protein concentrate 	 Alfalfa protein concentrate Medicago sativa protein concentrate 	N/A	Medicago sativa	Herb top
Casein	Casein	 Acid casein Calcium caseinate Calcium sodium caseinate Sodium caseinate 	Bos taurus	Milk



		Source information		
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)
Casein hydrolysateHydrolyzed casein	Casein hydrolysateHydrolyzed casein	N/A	Bos taurus	Milk
Casein micelles	Micellar casein	N/A	Bos taurus	Milk
Chickpea protein concentrate	Chickpea protein concentrate	N/A	Cicer arietinum	Seed
Cicer arietinum	Chick-peaGarbanzo	N/A	Cicer arietinum	Seed
Defatted wheat germ protein	Defatted wheat germ protein	N/A	Triticum aestivum	Seed germ
Fish protein hydrolysate	Fish protein hydrolysate	N/A	Clupea harengus	EggFish semenOvaryTestis
			Gadus chalcogrammus Gadus morhua	MeatMuscleMeat
			Merluccius productus	Meat
			Micromesistius poutassou	MeatMuscle
			Molva dypterygia	Meat
			Salmo salar	Meat
			Scomber scombrus	Meat
Flaxseed protein	Flaxseed protein	N/A	Linum usitatissimum	Seed
Hemp protein concentrate	Hemp protein concentrate	N/A	Cannabis sativa	Seed
Hemp protein isolate ¹	Hemp protein isolate	N/A	Cannabis sativa	Seed
Hemp seed protein	Hemp seed protein	N/A	Cannabis sativa	Seed
Milk protein concentrate	Milk protein concentrate	N/A	Bos taurus	Milk
Milk protein	Milk protein isolate	N/A	Bos taurus	Milk

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		Source information	n	
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)
isolate ¹				
Oryza sativa	Asian riceBlack ricePurple riceRice	N/A	Oryza sativa	Seed
Pea protein	Pea protein	N/A	Pisum sativum	Seed
Pea protein concentrate	Pea protein concentrate	N/A	Pisum sativum	Seed
Pea protein isolate ¹	Pea protein isolate	N/A	Pisum sativum	Seed
Pisum sativum	Pea	N/A	Pisum sativum	Seed
Potato proteinPotato tuber protein	Potato proteinPotato tuber protein	N/A	Solanum tuberosum	Tuber
Rice protein	Rice protein	N/A	Oryza sativa	Seed
Rice protein concentrate	Rice protein concentrate	N/A	Oryza sativa	Seed
Vicia faba	Fava bean	N/A	Vicia faba	Seed
Wheat protein isolate ¹	Wheat protein isolate	N/A	Triticum aestivum	Seed germ
Whey protein concentrate	Whey protein concentrate	N/A	Bos taurusCapra hircus	Milk
Whey protein hydrolysate	Whey protein hydrolysate	N/A	Bos taurusCapra hircus	Milk
Whey protein isolate ¹	Whey protein isolate	N/A	Bos taurusCapra hircus	Milk

¹For isolate, the potency information should be equivalent to 90% or more protein on a dry weight basis.

Group 2: Amino acids

Group 2a: Essential amino acids

Proper name(s)	Common name(s)	Source information
1 Toper name(s)	Common name(s)	Source ingredient(s)
` ' 1		L-Histidine
imidazole-4-propanoic acid		L-Histidine hydrochloride
► L-Histidine		





D	C(-)	Source information
Proper name(s)	Common name(s)	Source ingredient(s)
► (2S,3S)-2-Amino-3-	L-Isoleucine	► L-Isoleucine
methylpentanoic acid		L-Isoleucine ethyl ester
► L-Isoleucine		L-Isoleucine ethyl ester
		hydrochloride
		L-Isoleucine hydrochloride
		N-Acetyl-L-isoleucine
► (S)-2-Amino-4-	L-Leucine	L-Leucine hydrochloride
methylpentanoic acid		L-Leucine
► L-Leucine		L-Leucine ethyl ester
		L-Leucine ethyl ester
		hydrochloride
		L-Leucine methyl ester
		hydrochloride
		N-Acetyl-L-leucine
		N-Glycyl-L-leuc ine
► (S)-2,6-Diaminohexanoic	► L-Lysine	► L-Lysine
acid	▶ Lysine	▶ L-Lysine-L-aspartate
► L-Lysine		► L-Lysine monohydrochloride
		► L-Lysine acetate
		► L-Lysine dihydrochloride
► (S)-2-Amino-4-	L-Methionine	▶ DL-Methionine
(methylthio)butanoic acid	Methionine	► L-Methionine
► L-Methionine		► N-Acetyl-L-methionine
► (S)-2-Amino-3-	L-Phenylalanine	▶ DL-Phenylalanine
phenylpropanoic acid		▶ L-Phenylalanine
► L-Phenylalanine		► L-Phenylalanine methyl ester
		▶ N-Acetyl-L-phenylalanine
► (2S,3R)-2-Amino-3-	L-Threonine	▶ DL-Threonine
hydroxybutyric acid		► L-Threonine
► L-Threonine		
► (S)-alpha-Amino-1H-	► L-Tryptophan	L-Tryptophan
indole-3-propanoic acid	Tryptophan	
L-alpha-Aminoindole-3-		
propionic acid		
► L-Tryptophan ► (S)-2-Amino-3-	L-Valine	▶ DL-Valine
methylbutanoic acid	L-vamic	L-Valine
L-Valine		L-Valine ethyl ester
		L-Valine ethyl ester
		hydrochloride
		► L-Valine hydrochloride
		► N-Acetyl-L-valine





Group 2b: Non-essential amino acids

D	C(-)	Source information
Proper name(s)	Common name(s)	Source ingredient(s)
(S)-2-Aminopropanoic acidL-Alanine	L-Alanine	 Alanylglutamine DL-Alanine L-Alanine L-Alanine ethyl ester hydrochloride
 3-Aminopropanoic acid 3-Aminopropionic acid beta-Aminopropionic acid 	beta-Alanine	beta-Alaninebeta-Alanine ethyl ester
 ▶ (S)-2-Amino-5 [(aminoiminomethyl)amino] pentanoic acid ▶ L-Arginine 	L-Arginine	 DL-Arginine L-Arginine alpha- ketoglutarate L-Arginine ketoisocaproic acid L-Arginine monohydrochloride
(S)-2,4-Diamino-4- oxobutanoic acidL-Asparagine	L-Asparagine	L-Asparagine
(S)-Aminobutanedioic acidL-Aspartic acid	L-Aspartic acid	 L-Aspartic acid Potassium aspartate Potassium magnesium aspartate
 (S)-N5-Carbamoylornithine L-Citrulline N5-(Aminocarbonyl)-L- ornithine 	➤ Citrulline ► L-Citrulline	 L-Citrulline ethyl ester L-Citrulline malate L-Citrulline
(R)-2-Amino-3- mercaptopropanoic acidL-Cysteine	L-Cysteine	 L-Cysteine hydrochloride L-Cysteine hydrochloride monohydrate D-Ribose-L-cysteine L-Cysteine
(S)-2-Aminopentanedioic acidL-Glutamic acid	L-GlutamateL-Glutamic acid	 L-Glutamic acid hydrochloride L-Glutamic acid Monosodium L-glutamate
(S)-2,5-Diamino-5- oxopentanoic acidL-Glutamine	GlutamineL-Glutamine	▶ L-Glutamine▶ L-Glutamine ethyl ester
Aminoacetic acid	Glycine	GlycineGlycine hydrochlorideN-Glycyl-L-leucine
(S)-2-Pyrrolidinecarboxylic acidL-Proline	L-Proline	L-Proline

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Duoman mana(a)	Common nome(s)	Source information	
Proper name(s)	Common name(s)	Source ingredient(s)	
► (S)-2-Amino-3- hydroxypropanoic acid ► L-Serine	L-Serine	L-Serine	
 (S)-alpha-Amino-4- hydroxybenzenepropanoic acid L-Tyrosine 	➤ L-Tyrosine ➤ Tyrosine	▶ L-Tyrosine▶ L-Tyrosine ethyl ester▶ N-Acetyl-L-tyrosine	

Group 3: Carbohydrates

		Source information			
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)	
D-Fructose	D-Fructose	N/A	Malus domestica	Fruit	
		D-Fructose	N/A	N/A	
D-Galactose	D-Galactose	D-Galactose	N/A	N/A	
D-Glucose	DextroseD-GlucoseGlucose	D-Glucose monohydrateGlucose	N/A	N/A	
4-O-beta-D- Galactopyrano syl-D-glucose	Lactose	Lactose	N/A	N/A	
Maltodextrin	Maltodextrin	Maltodextrin	N/A	N/A	
D-Mannose	D-Mannose	D-Mannose	N/A	N/A	
Solanum tuberosum	Potato starchStarch - Potato	N/A	Solanum tuberosum	Tuber	
Oryza sativa ¹	Rice starchStarch - Rice	N/A	Oryza sativa	Seed	
D-Ribose	D-RiboseRibose	D-Ribose L- cysteineRibose	N/A	N/A	
▶ alpha-D-	Cane sugar	N/A	Acer saccharum	Sap	
Glucopyranosyl- beta-D- fructofuranoside	SaccharoseSucrose		Beta vulgaris	Root	
beta-D- Fructofuranosyl-	► Sugar		Borassus flabellifer	Sap	
alpha-D- glucopyranoside			Malus domestica	Fruit	
			Oryza sativa	Seed	

		Source information			
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)	
			Saccharum officinalis	Leaf stalk	
Triticum aestivum ¹	Starch - WheatWheat starch	N/A	Triticum aestivum	Seed endosperm	
Zea mays ¹	Corn starchStarch – MaizeZea mays starch	N/A	Zea mays	Seed	
Zea mays ¹	Waxy maize starch	N/A	Zea mays	Seed	

¹Starch ingredients should be prepared (e.g., gelatinized) such that carbohydrates are readily absorbable.

Group 4: Ergogenic agents

Group 4a: Non-Caffeinated ergogenic agents

		Source information	n		
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
Calcium beta-hydroxy- beta-methylbutyrate	CaHMBCalcium beta- hydroxy-beta- methylbutyrate	 Calcium beta- hydroxy-beta- methylbutyrate Calcium beta- hydroxy-beta- methylbutyrate monohydrate 	N/A	N/A	N/A
 (L-3-Carboxy-2-hydroxypropyl) trimethylammonium hydroxide, inner salt (R)-3-Carboxy-2-hydroxy-N,N,N-trimethyl-1-propanaminium hydroxide, inner salt L-Carnitine Levocarnitine 	▶ L-Carnitine▶ Levocarnitine	 L-Carnitine fumarate L-Carnitine tartrate 	N/A	N/A	N/A
N-(Aminoiminomethyl)- N-methylglycine monohydrate	Creatine monohydrate	Creatine monohydrate	N/A	N/A	N/A
Eleutherococcus senticosus	Ci wu jiaEleutheroSiberian ginseng	N/A	Eleutheroc occus senticosus	Root	Dry
Panax ginseng	Asian ginsengChinese ginsengHong shen	N/A	Panax ginseng	RootRootlet	Dry

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		Source information			
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
	 Korean ginseng Korean red ginseng Oriental ginseng Panax ginseng Red ginseng Ren shen 				

Group 4b: Caffeine

D ()		Source information	
Proper name(s)	Common name(s)	Source ingredient(s)	
 1,3,7-Trimethylxanthine 3,7-Dihydro-1,3,7-trimethyl-1H-purine-2,6-dione 	Caffeine	CaffeineCaffeine citrate	

Group 5: Vitamins and Minerals

D		Source information	
Proper name(s)	Common name(s)	Source ingredient(s)	
As per the current NNHPD Multi-Vitamin/Mineral Supplement monograph			

Group 6: Complementary ingredients

	Common	Source informati	on		
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
1-Amino-4- guanidinobutane4-(Aminobutyl)guanidine	Agmatine	Agmatine sulfate	N/A	N/A	N/A
Malpighia glabra	AcerolaBarbados cherry treeEscobillo	N/A	Malpighia glabra	Fruit	DryFresh
Piper nigrum	Black pepperPepper- blackPepper- white	N/A	Piper nigrum	Fruit	Dry

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	Common	Source information	on		
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
	► White pepper				
 (beta- Hydroxyethyl)trimethyla mmonium 2-Hydroxy-N,N,N- trimethylethanaminium Choline 	Choline	 Choline Choline alfoscerate Choline bitartrate Choline chloride Choline citrate Choline dihydrogen citrate Choline 	N/A	N/A	N/A
Capsicum annuum	 Cayenne Cayenne pepper Chili pepper Paprika Red Pepper 	N/A	Capsicum annuum	Fruit	Dry
all-trans-Lycopene	Lycopene	N/A	Solanum lycopersic um	Fruit flesh	N/A
		Lycopene	N/A	N/A	
 (S)-2,5-Diaminopentanoic acid (S)-alpha,delta-Diaminovaleric acid 	L-Ornithine	 L-Ornithine L-Ornithine hydrochloride L-Ornithine-L-aspartate Ornicetil 	N/A	N/A	N/A
2-Aminoethanesulfonic acid	Taurine	L-Arginine taurinateTaurineTaurine ethyl ester	N/A	N/A	N/A

References: NHPID 2019.





Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the webbased Product Licence Application form for Compendial applications.

Note

Liquids and solutions are not permitted for products containing Creatine monohydrate, due to lack of stability of the finished product (Dash and Sawhney 2002).

Use(s) or Purpose(s)

Note

See Ingredient Combination section below.

Products providing at least 2.6 g of protein and/or amino acids from Groups 1, 2a and 2b

- ► Workout supplement
- ► Athletic support
- ▶ Assists in the building of lean muscle tissue/mass when combined with regular weight/resistance training and a healthy balanced diet (NNHPD 2019).

Products containing at least one ingredient from any of Groups 3 or 4a, at or above the relevant minimum doses indicated in the Dose section below

- Workout supplement
- ► Athletic support

Products containing at least one ingredient from Group 1, at or above the minimum dose indicated in the Dose section below

- ▶ Source of protein for the maintenance of good health (CFIA 2019).
- ▶ Source of protein which helps build and repair body tissues (CFIA 2019).
- ▶ Source of amino acids involved in muscle protein synthesis (IOM 2005).





Products containing at least one ingredient from Group 2a, at or above the respective minimum dose indicated in the Dose section below

- ▶ Source of (an) essential amino acid(s) for the maintenance of good health (CNF 2019).
- ▶ Source of (an) (essential) amino acid(s) involved in muscle protein synthesis (IOM 2005).

Products containing all three of L-leucine, L-isoleucine and L-valine, at or above the respective minimum doses indicated in the Dose section below

Source of branched chain amino acids (BCAAs), which are involved in protein synthesis (IOM 2005).

Products containing at least one ingredient from Group 2b, at or above the respective minimum dose indicated in the Dose section below

Source of (an) (non-essential) amino acid(s) involved in muscle protein synthesis (IOM 2005).

Products containing Beta-Alanine, at or above a minimum dose of 800 mg per single dose and 4.8 g, per day

Increases muscle carnosine levels, a factor in delaying neuromuscular fatigue in intermittent high intensity exercises (Hoffman et al. 2008; Hills et al. 2007; Derave et al. 2007; Harris 2006; Stout et al. 2006).

Products containing L-glutamine, at or above a minimum dose of 5 g, per day

- ▶ Helps restore plasma glutamine levels depleted after periods of physical stress (e.g. prolonged exhaustive exercise) (Krzywkowski et al. 2001; Bowtell et al. 1999; Castell and Newsholme 1997).
- ▶ Helps to assist in muscle cell repair after exercise (Newsholme et al. 2003; IOM 2005).

Products containing at least one ingredient from Group 3, at or above the minimum dose indicated in the Dose section below

- ▶ Source of carbohydrates to support energy production (IOM 2005).
- ▶ Source of calories which contributes to weight gain (IOM 2005).
- ▶ Helps to maintain performance/promote endurance in extended (greater than 60 min), high intensity exercise (Kerksick et al. 2008).

Products containing at least one ingredient from Group 4a, at or above the relevant minimum doses indicated in the Dose section below

Helps increase physical performance during intensive exercise (NNHPD 2019).





Additionally, the following recommended uses may be indicated for products containing the corresponding medicinal ingredients, at or above the relevant minimum doses indicated in the Dose section below:

Calcium beta-hydroxy-beta-methylbutyrate (CaHMB)

Enhances muscle strength in previously untrained individuals in combination with intense resistance training exercise (NNHPD 2019).

L-Carnitine sourced from L-Carnitine tartrate

- ▶ Aids in the muscle recovery process by reducing muscle tissue damage associated with a resistance training regimen (Ho et al. 2010; Spiering et al. 2008; Spiering et al. 2007; Kraemer et al. 2006; Kramer et al. 2003; Volek et al. 2002).
- ▶ Helps support muscle tissue repair in individuals involved in resistance training (Ho et al. 2010; Spiering et al. 2008; Spiering et al. 2007; Kraemer et al. 2006; Kramer et al. 2003; Volek et al. 2002).
- ▶ Helps improve physical performance when used in conjunction with a training regimen (Wall et al. 2011; Cha et al. 2001; Arenas et al. 1994; Huertas et al. 1992; Arenas et al. 1991; Vecchiet et al. 1990; Marconi et al. 1985).
- ▶ Helps delay fatigue during physical activity (Cha et al. 2011; Wall et al. 2011; Karahan et al. 2010).
- ▶ Helps support fat metabolism (Stephens et al. 2007; Karlic and Lohninger 2004; Müller et al. 2002).
- ▶ Helps support fat oxidation (Wall et al. 2011; Stephens et al. 2007; Wutzke and Lorenz 2004; Müller et al. 2002).
- ▶ Helps support fat metabolism and oxidation (Wall et al. 2011; Stephens et al. 2007; Karlic and Lohninger 2004; Wutzke and Lorenz 2004; Müller et al. 2002).
- ▶ Workout support/supplement that helps improve physical performance when used in conjunction with a training regimen (Wall et al. 2011; Cha et al. 2001; Arenas et al. 1994; Huertas et al. 1992; Arenas et al. 1991; Vecchiet et al. 1990; Marconi et al. 1985).
- ▶ Workout support/supplement that delays fatigue during physical activity (Wall et al. 2011; Stephens et al. 2007; Karlic and Lohninger 2004; Müller et al. 2002; Cha et al. 2001; Arenas et al. 1994; Huertas et al. 1992; Arenas et al. 1991; Vecchiet et al. 1990; Marconi et al. 1985).

Products containing L-Citrulline at or above a minimum dose of 3 g, per day

L-Citrulline is a precursor of L-Arginine (Ochiai et al. 2012; Waugh et al. 2001).

Products containing L-Citrulline sourced from Citrulline malate at or above a minimum dose of 1.7 g (equivalent to 3 g citrulline malate), per day

Supports an increase in athletic performance in high-intensity anaerobic exercise with short rest period (Perez-Guisado and Jakeman 2010; Bailey et al. 2015; Bendahan et al. 2002).





Creatine monohydrate

- ▶ Increases body/(lean)muscle mass/size when used in conjunction with a resistance training regimen (Brose et al. 2003; Bemben et al. 2001; Volek et al. 1999; Vandenberghe et al. 1997)
- ▶ Improves strength/power/performance in repetitive bouts of brief, highly-intense physical activity (e.g. sprints, jumping, resistance training) (by increasing muscle/intramuscular creatine/phosphocreatine/energy levels) (Okudan and Gökbel 2005; Brose et al. 2003; Preen et al. 2003; Bemben et al. 2001; Volek et al. 1999; Vandenberghe et al. 1997; Hultman et al. 1996)

Eleuthero/Siberian ginseng

Eleuthero/Siberian ginseng is used in Herbal Medicine to help improve physical performance after periods of physical exertion (Bradley 2006; ESCOP 2003; Hoffmann 2003; Mills and Bone 2000).

Panax ginseng

(Chinese/Korean/*Panax*) ginseng is used in Herbal Medicine to help enhance physical capacity/performance (in cases of physical stress) (Kim et al. 2005; ESCOP 2003; Gross et al. 2002; WHO 1999; Gross et al. 1995; Sotaniemi et al. 1995; Schepdael 1993).

Products containing Caffeine (Group 4b), at or above the minimum dose indicated in the Dose section below

- ▶ Helps (temporarily) to relieve fatigue, to promote endurance, and to enhance motor performance (Philip et al. 2006; Doherty and Smith 2005; Smith et al. 2005).
- ▶ Helps (temporarily) to enhance (physical) energy (Philip et al. 2006; Doherty and Smith 2005; Smith et al. 2005).
- ▶ Helps (temporarily) to reduce tiredness and fatigue (Philip et al. 2006; Doherty and Smith 2005; Smith et al. 2005).

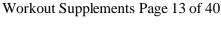
Additional claims

Products containing ingredients from Group 5, at or above the minimum doses indicated in the Dose section below

As per the current NNHPD Multi-Vitamin/Mineral Supplements Monograph.

Note

Claims from the NNHPD Multi-Vitamin/Mineral Supplements Monograph are only acceptable in addition to at least one claim from Groups 1 to 4.







Ingredient Combinations

All ingredients included in this monograph may be combined together, across all Groups, with the following restriction:

Products containing caffeine must indicate the recommended use or purpose for Group 4b, and may not indicate any recommended uses or purposes related to the maintenance/support of good/general health.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

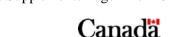
Note

The minimum doses indicated below must be met only for medicinal ingredients which are directly supporting any indicated uses or purposes, as per the Use(s) or Purpose(s) section above.

Table 2. Doses and methods of preparation for Group 1 (Proteins)¹

Medicinal Ingredients	Methods of	Doses	
Wedichiai ingredichts	preparation	Minimum/day	Maximum/day
Total amount of protein from	Isolate,	2.6 g	90 g
Group 1 + amounts of amino	Standardized		
acids from Groups 2a and 2b	extracts (Extract		
in the product	dry)		

Reference: IOM 2005.



¹ The potency of protein on an "as is" weight basis is required to be indicated on the Product License Application form and label for each medicinal ingredient from Group 1.



Table 3. Doses for Group 2a (Essential amino acids)

Medicinal Ingredients	Doses		
Wedicinal Ingredients	Minimum/day	Maximum/day ¹	
L-Histidine	49 mg	220 mg	
L-Isoleucine	66.5 mg	3,500 mg	
L-Leucine	147 mg	7,000 mg	
L-Lysine	133 mg	3,000 mg	
L-Methionine	66.5 mg	1,000 mg	
L-Phenylalanine	115.5 mg	339 mg	
L-Threonine	70 mg	301 mg	
L-Tryptophan	17.5 mg	220 mg	
L-Valine	84 mg	3,500 mg	

Reference: Doses: Verhoeven et al. 2009; Guttuso et al. 2008; IOM 2005; Coombes and McNaughton 2000; Bassit et al. 2002; Plaitakis et al. 1988; Berry et al. 1982.

Table 4. Doses for Group 2b (Non-essential amino acids)

Madiainal Inquadiants	Doses			
Medicinal Ingredients	Minimum/day	Maximum/day ¹	Maximum/single dose	
L-Alanine	181.5 mg	363 mg	N/A	
L-Arginine	208.5 mg	9,000 mg	N/A	
L-Asparagine	4.6 mg	93.5 mg	N/A	
L-Aspartic acid	325 mg	1,000 mg	N/A	
beta-Alanine	240 mg	6,400 mg	3,200 mg	
L-Citrulline	150 mg	6,000 mg	3,000 mg	
L-Cysteine	50 mg	1,000 mg	N/A	
L-Glutamic acid	750 mg	1,500 mg	N/A	
L-Glutamine	342.5 mg	9,000 mg	N/A	
Glycine	160 mg	1,800 mg	N/A	
L-Proline	259.5 mg	519 mg	N/A	
L-Serine	175.5 mg	351 mg	N/A	
L-Tyrosine	139 mg	3,600 mg	N/A	

References: Doses: NNHPD 2019, Lenders et al. 2009, IOM 2005, Derave et al. 2007, Hills et al. 2007 ¹When combining individual amino acids with protein ingredients, applicants must consider the contribution of the protein ingredient(s) to the total dose of each amino acid, in order to respect the maximum doses indicated above.



¹When combining individual amino acids with protein ingredients, applicants must consider the contribution of the protein ingredient(s) to the total dose of each amino acid, in order to respect the maximum doses indicated above.



Table 5. Doses for Group 3 (Carbohydrates)

Medicinal Ingredients	Doses			
Wedicinal Ingredients	Minimum/day	Maximum/day	Maximum/single dose	
Combined dose for all	6.5 g	180 g	45 g	
ingredients from Group 3 in				
the product				

Reference: Dietitians of Canada 2013

Table 6. Doses, methods of preparation and uses or purposes for Group 4a (Non-caffeinated ergogenic agents)

Madiated		M-41-16		Doses	
Medicinal Ingredients	Uses or purposes	Methods of preparation	Minimum/day	Maximum/day	Maximum/ single dose
Calcium beta- hydroxy-beta- methylbutyrate	Enhances muscle strength in previously untrained individuals in combination with intense resistance training exercise	N/A	3 g	6 g	N/A
L-Carnitine	Muscle recovery, Muscle tissue repair, Workout support/ supplement Physical performance, Fatigue, Workout support/supplement combined with Physical performance/Fatigue Fat metabolism, Fat oxidation	N/A	1 g 2 g	4 g	2 g
Eleutherococcus senticosus	Eleuthero/Siberian ginseng is used in Herbal Medicine to help improve physical performance after periods of physical exertion	Dry, Powder, Non- Standardised Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion)	0.91 g of dried root	6 g of dried root	N/A

Madiata 1		Made at a		Doses	
Medicinal Ingredients	Uses or purposes	Methods of preparation	Minimum/day	Maximum/day	Maximum/ single dose
Panax ginseng	(Chinese/Korean/ Panax) ginseng is used in Herbal Medicine to help enhance physical capacity/performance (in cases of physical stress)	Dry, Powder, Non- Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.5 g of dried root/rootlets	9 g of dried root/rootlets	N/A
		Standardized Extracts (Dry extract)	200 mg of extract standardized to 4-7% of total ginsenosides; Not to exceed 9 g of dried root/rootlets per day	600 mg of extract standardized to 4-7% of total ginsenosides; Not to exceed 9 g of dried root/rootlets per day	N/A

References: Doses: CaHMB: Rowlands and Thomson 2009, Gallagher et al. 2000a,b. Carnitine: Wall et al. 2011, Ho et al. 2010, Spiering et al. 2008, Spiering et al. 2007, Stephens et al. 2007, Kraemer et al. 2006, Karlic and Lohninger 2004, Wutzke and Lorenz 2004, Kramer et al. 2003, Müller et al. 2002, Volek et al. 2002, Benvenga et al. 2001, Cha et al. 2001, Ahmet et al. 2000, Arenas et al. 1994, Huertas et al. 1992, Arenas et al. 1991, Vecchiet et al. 1990, Harper et al. 1988, Marconi et al. 1985. Eleuthero: Bradley 2006, ESCOP 2003, Hoffmann 2003, Blumenthal et al. 2000, Mills and Bone 2000. Panax ginseng: Vuksan et al. 2008, Reay et al. 2006, Sievenpiper et al. 2006, Reay et al. 2005, Sünram-Lea et al. 2005, Kennedy et al. 2004, ESCOP 2003, Kennedy et al. 2002, Scholey and Kennedy 2002, Engels et al. 2001, Kennedy et al. 2001, Scaglione et al. 2001, Blumenthal et al. 2000, Tetsutani et al. 2000, McGuffin et al. 1997, Engels et al. 1996, Scaglione et al. 1996, Gross et al. 1995, Scaglione et al. 1994, Scaglione et al. 1990, Petkov and Mosharrof 1987, D'Angelo et al. 1986, Soldati and Sticher 1980.

Table 7. Doses and durations of use for creatine monohydrate

Medicinal	Phases				Durations of	
Ingredient			Minimum/day	Maximum/day	Maximum /single dose	use
Creatine		Option 1	15 g	20 g	5 g	5-7 days
monohydrate	Loading Phase	Option 2	3 g	5 g	N/A	Use for a minimum of 4 weeks
	Maintena	nce Phase	2 g	5 g	N/A	N/A

References: Doses: Option 1: Okudan and Gokbel 2005, Preen et al. 2003, Bemben et al. 2001,

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Vandenberghe et al. 1997, Hultman et al. 1996. Option 2: Hultman et al. 1996. Maintenance phase: Preen et al. 2003, Bemben et al. 2001, Volek et al. 1999, Vandenberghe et al. 1997, Hultman et al. 1996.

Table 8. Doses for Group 4b (Caffeine)1

Medicinal Ingredient		Doses	
Medicinal Highedient	Minimum/day	Maximum/day	Maximum/single dose
Caffeine	100 mg	400 mg	200 mg

Reference: HC 2012.

Table 9. Doses for Group 5 (Vitamins and Minerals)

Medicinal Ingredients	Doses
Vitamins and Minerals	As per the current NNHPD Multi-Vitamin/Mineral Supplements Monograph

Table 10. Doses and methods of preparation for Group 6 (Complementary ingredients)

Medicinal ingredients	Methods of preparation	Doses	
		Minimum/day	Maximum/day
Agmatine	N/A	> 0 mg	2,000 mg
Choline	N/A	> 0 mg	1,000 mg
Capsicum annuum	Dry, Powder, Non- Standardised Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion)	> 0 mg dried fruit	650 mg of dried fruit
Lycopene	N/A	> 0 mg	30 mg
L-Ornithine	N/A	> 0 mg	1,500 mg
Malpighia glabra	Dry, Powder, Non- Standardised Extracts (Dry extract, Tincture,	> 0 mg dried or fresh fruit	10 g of dried fruit
	Fluid Extract, Decoction, Infusion)		100 g of fresh fruit
Piper nigrum	Dry, powdered	> 0 mg dried fruit	25 mg of dried fruit
Taurine	N/A	> 0 mg	3,000 mg

References: Doses: NNHPD 2019; CNF 2019; Wong et al. 2016; Figueroa et al. 2015; Kenyan et al. 2010.



¹Maximum daily dose of 1000 milligrams from NNHPD Caffeine monograph does not apply for Workout Supplements as this maximum dose is not acceptable for prolonged use.



Direction(s) for use

All products (optional)

Ensure to drink optimal fluid before, during, and after exercise.

Products containing Creatine monohydrate and making Creatine claims

Phase(s)		Direction(s) for use	
Loading Phase	Option 1	Step 1 (Loading Phase): Start with a loading phase of 5-7 days (15-20 g/d) and follow with a maintenance phase (2- 5g/d)	
	Option 2	Step 1 (Loading Phase): Start with a loading phase of 4 weeks (3-5 g/d) and follow with a maintenance phase (2-5 g/d)	
Maintenance Phase		Step 2 (Maintenance Phase): No statement required	

Reference: NNHPD 2019.

Products containing L-Carnitine and making Muscle recovery, Muscle tissue repair, Workout support/supplement, Physical performance, or Fatigue claims

Take 2-4 hours prior to exercise (Harper et al. 1988).

Products providing more than 200 mg of caffeine, per day (i.e. to be taken in divided doses)

Wait 3 to 4 hours between each dose

Products containing Whey protein

Take a few hours before or after taking other medications or natural health products (Martindale 2009; Jung et al. 1997).

Products in powder form

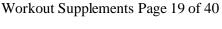
Mix product in enough liquid (water, juice, etc.) to ensure that the powder is drinkable immediately before consumption.

Products for increasing exercise performance (optional)

Consume 45-90 minutes before exercising (Aragon and Schoenfeld 2013).

Products for repairing body tissues/muscles and restoring plasma glutamine levels (optional)

Consume no later than 90 minutes after exercising (Aragon and Schoenfeld 2013).







Products for endurance based on ingredients from Group 3 (Carbohydrates) (optional)

Consume 30-60 grams of carbohydrates, per hour of high intensity exercise (Saunders et al. 2007; Ivy et al. 2003).

Products containing Vitamins and/or Minerals

As per the current NNHPD Multi-Vitamin/Mineral Supplements Monograph.

Duration(s) of use

Products providing more than 200 mg of Agmatine, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 3 weeks (Gilad and Gilad 2014; Kenyan et al. 2010).

Products providing 0.42 g and more of L-Arginine, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 weeks if you suffer from a cardiovascular disease (Shao and Hathcock 2008; Sydow et al. 2002; Hambrecht et al. 2000; Clarkson et al. 1996; Rector et al. 1996).

Products providing more than 3 g of L-Citrulline, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 8 weeks (Behpour et al. 2020; Wong et al. 2016; Figueroa et al. 2015).

Product providing more than 3 g of Beta-Alanine, per day

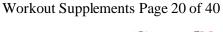
Consult a health care practitioner/health care provider/health care professional/doctor/ physician for use beyond 10 weeks (Derave et al. 2007; Hills et al. 2007).

Products containing Eleuthero

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 1 month (ESCOP 2003).

Products containing Panax ginseng

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 3 months (Bradley 2006; Mills and Bone 2005; Blumenthal et al. 2000; McGuffin et al. 1997).







Products containing Vitamins and/or Minerals

As per the current NNHPD Multi-Vitamin/Mineral Supplements Monograph.

Risk information

Caution(s) and warning(s)

All products

Consult a healthcare practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

Products containing milk by-products (such as casein/caseinates, whey and milk proteins)

This product contains milk by-products.

Products providing more than 30 g total protein and/or amino acids (including beta-alanine), per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have liver or kidney disease (Shils et al. 2006).

Products containing Caffeine

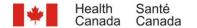
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have high blood pressure, glaucoma, and/or overactive bladder syndrome (detrusor instability) (Cornelis and El-Sohemy 2007, Chandrasekaran et al. 2005, Noordzij et al. 2005, Avisar et al. 2002, Arya et al. 2000, Jee et al. 1999, Creighton and Stanton 1990).
- ▶ Avoid taking with health products or foods that contain caffeine and/or increase blood pressure (e.g. medications, coffee, tea, colas, cocoa, guarana, mate, bitter orange extract, synephrine, ocotopamine, ephedra, ephedrine) (Bui et al. 2006; Bouchard et al. 2005; Haller et al. 2005; FDA 2004; Berardi et al. 2002; Vahedi et al. 2000; Zimmerman 1992; FDA 1988).
- ▶ This product is not intended as a substitute for sleep (Berardi et al. 2002, Zimmerman 1992, FDA 1988).

Products providing 200 mg or more of Caffeine, per day and recommended for endurance, motor performance, physical energy or to be taken prior to workout

Caffeine has been shown to reduce blood flow to the heart muscle during exercise which might lead to cardiovascular complications such as chest pain, and irregular heartbeat even in healthy individuals. Stop use and consult a health care practitioner/health care provider/health care

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professional/doctor/physician if those symptoms occur (Higgins and Babu 2013).

Products providing more than 300 mg of Caffeine, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician if you are of childbearing age, pregnant or breastfeeding (Nawrot et al. 2003).

Products containing CaHMB

Consult a health care practitioner /health care provider/health care professional/doctor/physician prior to use if you are taking medications for high cholesterol (Nissen et al. 2000).

Products containing Cayenne

- ▶ Keep out of reach of children.
- ▶ Call a Poison Control Center immediately if overdose or accidental ingestion occurs (CPS 2008).
- ► Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have stomach ulcers or inflammation (Brinker 2010; Bradley 2006; Boon and Smith 2004).

Products containing Creatine monohydrate

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you have kidney disease/disorder (Pline and Smith 2005; Pritchard and Kalra 1998).
- ▶ May result in weight gain (Volek and Rawson 2004; Bemben et al. 2001; Mihic et al. 2000

Products providing more than 200 mg of Agmatine, per day

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a mood/affective or psychiatric disorder, diabetes or a cardiovascular disease (Freitas et al. 2016; Nissim et al. 2014; Payandemehr et al. 2013; Piletz et al. 2013; Shopsin 2013; Uzbay et al. 2013; Su et al. 2003).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking antidepressant or opioid analgesic medications (Freitas et al. 2016; Payandemehr et al. 2013; Shopsin 2013; Uzbay et al. 2013; Su et al. 2003).

Products providing more than 0.42 g of L-Arginine, per day

▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you suffer from cardiovascular disease and are attempting an increase in physical activity or if your cardiovascular condition worsens (Doutreleau et al. 2010; Doutreleau et al. 2006; Schulman et al. 2006; Nagaya et al. 2001; Bednarz et al. 2000; Ceremuzynski et al. 1997; Rector et al. 1996).

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▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners (Huynh et al. 2002; Parker et al. 2002; Siani et al. 2000; Adams et al. 1995).

Products containing L-Carnitine

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a seizure disorder (CPS 2008).

Products containing Eleuthero

Consult a health care practitioner/health care provider/health care professional/doctor/physician if you have any type of acute infection (Brinker 2010; Barnes et al. 2007; ESCOP 2003; Mills and Bone 2000).

Products containing Panax ginseng

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you have diabetes (Brinker 2010; Vuksan et al. 2008; Seely et al. 2008; Sievenpiper et al. 2006; ESCOP 2003; Tetsutani et al. 2000; Sotaniemi et al. 1995; Chin 1991).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking antidepressant medication, blood thinners or digoxin (Brinker 2010; Lee et al. 2008a; Dasgupta and Reyes 2005; Janetzki and Morreale 1997; Gonzalez-Seijo et al. 1995; Shader and Greenblatt 1988; Jones and Runikis 1987; Shader and Greenblatt 1985).

Products containing Vitamins and/or Minerals

As per the current NNHPD Multi-Vitamin/Mineral Supplements Monograph.

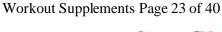
Contraindication(s)

Products providing more than 0.42 g of L-Arginine, per day

Do not use this product if you have had a heart attack/myocardial infarction (Schulman et al. 2006).

Products containing Eleuthero

Do not use this product if you have high blood pressure (Brinker 2010; Barnes et al. 2007; Blumenthal et al. 2000; Mills and Bone 2000; McGuffin et al. 1997).







Products containing Vitamins and/or Minerals

As per the current NNHPD Multi-Vitamin/Mineral Supplements Monograph.

Known adverse reaction(s)

Products containing beta-Alanine

Reduce the dose if flushing, tingling and/or prickling sensation of the skin occurs (Harris et al. 2006; Hill et al. 2007; Jordan et al. 2010)

Products containing Caffeine

Stop use if hypersensitivity/allergy occurs (Infante et al. 2003; Hinrichs et al. 2002).

Products providing more than 200 mg of Agmatine, per day or more than 0.42 g of L-Arginine, per day or more than 30 g of protein and/or amino acids, per day

Some people may experience gastrointestinal discomfort/disturbances (Keynan et al. 2010; Grimble 2007; Evans et al. 2004; Clarkson et al. 1996).

Products containing Panax ginseng

Stop use if you experience insomnia, anxiety or headaches (Lee et al. 2008b; Vuksan et al 2008; de Andrade et al. 2007; Sievenpiper et al. 2006; Coon and Ernst 2002; Ellis and Reddy 2002; Scaglione et al. 2001; Siegel 1979).

Products containing Vitamins and/or Minerals

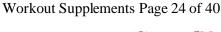
As per the current NNHPD Multi-Vitamin/Mineral Supplements Monograph.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Store in a cool, dry place.







Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

Hemp protein, Hemp protein isolate and Hemp seed protein

Must not contain more than 10 parts per million delta-9-Tetrahydrocannabinol (THC), or phytocannabinoids that have been isolated or concentrated. The determination of the THC concentration must take into account the potential to convert delta-9-tetrahydrocannabinolic acid (THCA) to THC. These hemp derivatives must also be compliant with the Industrial Hemp Regulations (IHR). All sources of hemp falling under the IHR are expected to be of an approved cultivar, defined in the IHR as any variety of industrial hemp set out in the List of Approved Cultivars, published by the Government of Canada on its website, as amended from time to time. (GC 2018a; GC 2018b; GC 2003; HC 2019; HC 2018)

Creatine monohydrate

The finished product and/or raw material specifications must have limits for the following impurities: not more than 100 ppm creatinine; not more than 50 ppm dicyandiamide; non-detectable dihydrotriazine. The method used to detect dihydrotriazine must have a limit of detection of not more than 5 ppm.

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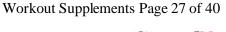
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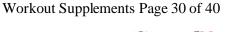
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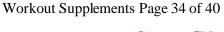
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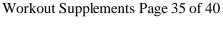
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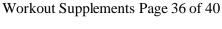
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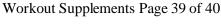
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