

NATURAL HEALTH PRODUCT

COGNITIVE FUNCTION PRODUCTS

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 described within.

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

April 26, 2024

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

Table 1.1. Proper name(s), Common name(s), Source information for ingredients with nervine action

D		Source information			
Proper name(s)	Common name(s)	Source material(s)	Part(s)	Preparation(s)	
Anemone pulsatilla	European pasqueflowerPasqueflowerPulsatilla	Anemone pulsatilla	Herb top	Dry ¹	
Avena sativa	 Common oat Oat Red oat Side oat Tree oat 	Avena sativa	SeedHerb top	Dry	
Hypericum perforatum	 Goatweed Hypericum St. John's wort St. John's-wort 	Hypericum perforatum	Herb top	Dry	
 5-Hydroxy-L- tryptophan 	L-5-HTPL-5-Hydroxytryptophan	Griffonia simplicifolia ²	Seed	N/A	
 L-5- Hydroxytrypto 		Saccharomyces cerevisiae	Whole cell for biosynthesis	N/A	
pilaii		Escherichia coli	Whole cell for biosynthesis	N/A	
Nepeta cataria	 Catmint Catnep Catnip Catswort Field balm 	Nepeta cataria	Herb top	Dry	



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		Source information			
Proper name(s)	Common name(s)	Source material(s)	Part(s)	Preparation(s)	
Matricaria chamomilla	 Blue chamomile Chamomile Common chamomile German chamomile Hungarian chamomile Matricaria Scented chamomile Scented mayweed Sweet false chamomile True chamomile Wild chamomile 	Matricaria chamomilla	Flower	Dry	
Melissa officinalis	BalmBee balmLemon balmMelissa	Melissa officinalis	Herb top	Dry	
Panax quinquefolius	 American ginseng Occidental ginseng Sang Shang Xi yang shen 	Panax quinquefolius	Root	Dry	
Scutellaria lateriflora	 Helmet flower Hoodwort Mad-dog scullcap Quarter bonnet Scullcap Skullcap Virginian skullcap 	Scutellaria lateriflora	Herb top	Dry	
Stachys officinalis	Bishop's-wortPurple betonyWood betony	Stachys officinalis	Herb top	Dry	
Tilia cordata	 Linden Littleleaf linden Small-leaf European linden Small-leaf lime Small-leaf lime tree Small-leaf linden Tilia 	Tilia cordata	Flower	Dry	
Tilia platyphyllos	 Big-leaf linden Broadleaf lime Large-leaf lime Large-leaf linden Linden Tilia 	Tilia platyphyllos	Flower	Dry	



		Source information			
Proper name(s)	Common name(s)	Source material(s)	Part(s)	Preparation(s)	
Tilia x europaea	 European Lime tree European linden Lime Lime tree Linden Tilia 	Tilia x europaea	Flower	Dry	
Turnera diffusa	Damiana	Turnera diffusa	LeafLeaf and stem	Dry	
Withania somnifera	 Asgandh Ashwagandha Asvagandha Winter-cherry Withania 	Withania somnifera	Root	Dry	

References: Proper names: NHPID 2023; Common names: NHPID 2023; Source information: EMA 2008; Bone 2003; Hoffman 2003; Lemaire and Adosraku 2002; API 2001; Bradley 1992; Williamson et al. 1988; BHP 1983; Fellows and Bell 1970; Remington and Wood 1918; BPC 1911.

¹Do not use the fresh plant (Bone 2003; Hoffman 2003; Bradley 1992; BHP 1983).

²Isolate. The source information for L-5-Hydroxytryptophan can also be synthetic.

Table 1.2	. Proper name(s),	Common name(s),	Source information	for ingredients	with sedative
action					

Proper name(s)	Common name(s)	Source information			
Troper name(s)		Source material(s)	Part(s)	Preparation(s)	
Eschscholzia californica	California-poppy	Eschscholzia californica	Herb top	Dry	
Humulus lupulus	 Bine European hop Hop Hops 	Humulus lupulus	Strobile	Dry	
Passiflora incarnata	 Apricot-vine Maypop Maypop passionflower Passionflower 	Passiflora incarnata	Herb top	Dry	
Valeriana officinalis	 Common valerian Garden-heliotrope Garden valerian Valerian 	Valeriana officinalis	 Root Root and rhizome 	Dry	

References: Proper names: NHPID 2023; Common names: NHPID 2023; Source information: Hoffman 2003; Williamson et al. 1988.



Table 1.3. Proper name(s), Common name(s), Source information for ingredients with cognitive support action

	Common	Source information				
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Organism group(s)	Part(s)	Preparation(s)
(2R)-2- (Acetyloxy)- 3- carboxy-N,N,N- trimethyl-1- propanaminium inner salt	Acetylcarnitine	 Acetyl-L- carnitine arginate dihydrochlo ride¹ Acetyl L- carnitine hydrochlorid e¹ 	N/A	N/A	N/A	N/A
Bacopa monnieri	BacopaMoneywortWater hyssop	N/A	Bacopa monnieri	N/A	Herb topWhole plant	Dry
 2-[[[(2R)-2,3- Dihydroxypropox y]hydroxyphosph inyl]oxy]-N,N,N- trimethylethanam inium hydroxide inner salt d-Choline hydroxide 2,3- dihydroxypropylh ydrogen phosphate inner salt L-alpha- Glycerylphosphor ylcholine 	Choline alfoscerate	Choline alfoscerate ¹	N/A	N/A	N/A	N/A
 Choline cytidine 5'-pyrophosphate (ester) Cytidine 5'- (trihydrogen diphosphate) P'- [2(trimethylammo nio)ethyl] ester inner salt Cytidine 5'- diphosphocholine 	Citicoline	 Citicoline sodium¹ Citicoline¹ 	N/A	N/A	N/A	N/A
Cod liver oil	 Cod liver oil Lecoris Aselli Oleum 	N/A	N/A	Gadidae ³	Liver	N/A



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	Common	Source information				
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Organism group(s)	Part(s)	Preparation(s)
Eleutherococcus senticosus	 Ci wu jia Eleuthero Siberian ginseng 	N/A	Eleutheroc occus senticosus	N/A	Root	Dry
Fish oil	Fish oil	N/A	N/A	 Ammodytid ae Carangidae Clupeidae Engraulidae Gadidae³ Osmeridae Salmonidae Scombridae 	Whole	N/A
Ginkgo biloba	 Ginkgo Ginkgo biloba Maidenhair- tree Baiguo Icho 	N/A	Ginkgo biloba	N/A	Leaf	N/A
Panax ginseng	 Asian ginseng Chinese ginseng Hong shen Korean ginseng Korean red ginseng Oriental ginseng Panax ginseng Red ginseng Ren shen 	N/A	Panax ginseng	N/A	• Root • Rootlet	Dry
Phosphatidyl serine	Phosphatidyl serine	N/A	Helianthus annuus ²	N/A	Seed	N/A
		Phosphatidylse rine-enriched soy lecithin ¹ Phosphatidylse	N/A N/A	N/A N/A	N/A N/A	N/A N/A
		rine ¹			1.11.1	11/11
Rhodiola rosea	 Hong jing tian King's-crown Rhodiola Roseroot 	N/A	Rhodiola rosea	N/A	 Root Root and rhizome 	Dry

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	Common	Source information				
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Organism group(s)	Part(s)	Preparation(s)
Schizochytrium spp.	Schizochytrium Oil	N/A	Schizochytr ium spp.	N/A	Whole	N/A
 (S)-alpha- Amino-4- hydroxybenzene propanoic acid L-Tyrosine 	 L-Tyrosine Tyrosine	 L-Tyrosine ethyl ester¹ N-Acetyl-L- tyrosine¹ 	N/A	N/A	N/A	N/A
Withania somnifera	 Asgandh Ashwagandha Asvagandha Winter-cherry Withania 	N/A	Withania somnifera	N/A	Root	Dry

References: Proper names: NHPID 2023; Common names: NHPID 2023; Source information: NHPID 2023; Yurko-Mauro et al. 2010; Calabrese et al. 2008; Bone 2003; De Jesus Moreno Moreno 2003; API 2001; Parnetti et al. 2001; Barbagallo et al. 1994; Parnetti et al. 1993; Canal et al. 1991. ¹Synthetic

²Isolate

³For cod liver oil and fish oil, the species common name can be listed as source information on the label instead of the organism group. Fish oil corresponds to oil from the whole body of one or more of species of the families listed in the table in its natural and/or concentrated triglyceride/triacylglycerol form and/or its concentrated esterified form.

Table 1.4. Proper name(s),	Common name(s),	Source informati	on for caffein	e and ingredients
containing caffeine				

	Common	Source information			
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
• 1,3,7- Trimethylxanth ine 2,7 Dibydra	Caffeine	 Caffeine¹ Caffeine citrate¹ 	N/A	N/A	N/A
• 3,7-Dinydro- 1,3,7- trimethyl-1H-		N/A	Camellia sinensis ²	Leaf	N/A
purine-2,6- dione		N/A	 Coffea arabica² Coffea canephora² 	Seed	N/A
		N/A	• Cola acuminata ²	Seed	N/A
		N/A	 Ilex paraguariensis² Ilex guayusa² 	Leaf	N/A
		N/A	• Paullinia cupana ²	Seed	N/A



	Common	Source information			
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
		N/A	 Theobroma cacao² 	Seed	N/A
Ilex paraguariensis	 Brazilian tea Mate Paraguayan tea Paraguay tea St Bartholomew's tea Yerba mate 	N/A	Ilex paraguariensis	Leaf	Dry
Paullinia cupana	Guarana	N/A	Paullinia cupana	Seed	Dry

References: Proper names: NHPID 2023; Common names: NHPID 2023; Source information: EMA 2013; ESCOP 2009; Bradley 2006; Kennedy et al. 2004; Taylor 2003; Barnes et al. 2002; BHP 1983. ¹Synthetic

²If caffeine is sourced from *Camellia sinensis*, *Coffea arabica*, *Coffea canephora*, *Cola acuminata*, *Ilex paraguariensis*, *Ilex guayusa*, *Paullinia cupana* or *Theobroma cacao*, it must be isolated and purified. Extracts of *Ilex paraguariensis* and *Paullinia cupana* must be represented separately. This monograph does not support extracts of *Camellia sinensis*, *Coffea arabica*, *Coffea canephora*, *Cola acuminata*, *Ilex guayusa* or *Theobroma cacao*.

Table 1.5. Proper name(s), Common name(s), Source information for ingredients with relaxation action

		Source information				
Proper name(s)	Common name(s)	Source ingredient(s)	Source material(s)	Part(s)		
4- Aminobutanoic acid GA gan Am	GABAgamma-	N/A	Lentilactobacillus hilgardii ²	Whole cell for biosynthesis		
	Aminobutyric acid	N/A	Levilactobacillus brevis ²	Whole cell for biosynthesis		
		N/A	Laminaria japonica ²	Whole		
		4-Aminobutanoic acid ¹	N/A	N/A		
• L-Theanine	L-Theanine	N/A	<i>Camellia sinensis</i> ²	Leaf		
glutamine		L-Theanine ¹	N/A	N/A		

References: Proper names: NHPID 2023; Common names: NHPID 2023; Source information: Kanehira et al. 2011; Abdou et al. 2006; Yamakoshi et al. 2006.

¹Synthetic

²Isolate



Table 1.6. Proper name(s), Common name(s), Source information for ingredients with adaptogen action

Proper name(s)	Common name(s)	Source information		
Toper name(s)	Common name(s)	Source material(s)	Part(s)	Preparation(s)
Asparagus racemosus	• Shatamuli	Asparagus racemosus	Root	Dry
	Shatavari	4	D (2
Astragalus membranaceus	Astragalus	Astragalus	Root	Dry
memoranaeeus	• Huangqi	memoranaceus		
	 Membranaceus milk 			
	vetch			
	• Membranous milk-vetch			
	• Milk vetch root			
	 Mo jia huang qi 			
Eleutherococcus	• Ci wu jia	Eleutherococcus	• Root	Dry
senticosus	• Eleuthero	senticosus	• Root and	
	• Siberian ginseng		rhizome	
Ganoderma lucidum	• Ganoderma	Ganoderma lucidum	• Cultured	Dry
	• Ling zhi		mycelium	
	• Reisni		• Fruiting	
			body Mysalium	
Glvcvrrhiza glabra	 Guang guo gan cao 	Glycyrrhiza glahra	Root	Drv
	Licorice		• Root and	2-15
	 Liquorice 		stolon	
Ocimum tenuiflorum	 Holy basil 	Ocimum tenuiflorum	Leaf	Dry
	 Rama tulsi 			
	 Sacred basil 			
	• Tulsi	D		2
Panax ginseng	• Asian ginseng	Panax ginseng	Root Root	Dry
	Chinese ginseng Hong shop		• Kootlet	
	 Korean ginseng 			
	 Korean red ginseng 			
	Oriental ginseng			
	 Panax ginseng 			
	• Red ginseng			
	Ren shen			
Panax quinquefolius	American ginseng	Panax quinquefolius	Root	Dry
	Occidental ginseng			
	 Sang Shang 			
	 Silally Xi yang shen 			
			1	



Proper name(s)	Common name(s)	Source information			
T Toper name(s)	Common name(s)	Source material(s)	Part(s)	Preparation(s)	
Rhodiola rosea	 Hong jing tian King's-crown Rhodiola Roseroot 	Rhodiola rosea	 Root Root and rhizome 	Dry	
Schisandra chinensis	Chinese MagnoliavineSchisandraWu wei zi	Schisandra chinensis	Fruit	Dry	
Tinospora cordifolia	Guduchi	Tinospora cordifolia	Stem	Dry	
Withania somnifera	 Asgandh Ashwagandha Asvagandha Winter-cherry Withania 	Withania somnifera	 Root Whole plant 	Dry	

References: Proper names: NHPID 2023; Common names: NHPID 2023; Source information: Upton 2012; Winston and Kuhn 2008; Winston and Maimes 2007; WHO 2004; Bone 2003; Hoffman 2003; Thomsen 2002; Williamson 2002; API 2001; Blumenthal et al. 2000; Upton 1999; WHO 1999; Bradley 1992; BHP 1983.

Table 1 7	7 Dro	nor nomola) Commor	nomo(c)	Source	information	for com	nlamontar	ingradiants
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	Common	Source information			
Proper name(s)	name(s)	Source ingredient(s)	Source material(s)	Part(s)	Preparation(s)
[5R-(5alpha,9beta, 11E)]-5-Amino-11- ethylidne-5,6,9, 1- tetrahydro-7- methyl-5,9- methano cycloocta [b]pyridine-2(1H)- one	Huperzine A	Huperzine A ¹	Huperzia serrata ²	Whole plant	Dry
7,9-Dihydro- 1,3,7,9-tetramethyl-	Theacrine	Theacrine ¹	Camellia sinensis ²	Leaf	Dry
2,6,8(3H)-trione			Theobroma grandiflorum ²	Fruit	Dry
 3,7-Dihydro-3,7- dimethyl-1H- purine-2,6-dione 3,7- Dimethylxanthine 	Theobromine	N/A	Theobroma cacao	Seed	Dry
Huperzia serrata	 Toothed club-moss Toge-shiba 	N/A	Huperzia serrata	Whole plant	Dry

References: Proper names: NHPID 2023; Common names: NHPID 2023; Source information: NHPID 2023; DNP 2017; Martinez-Pinilla et al. 2015; Ma et al. 2007; Kihlman 1977. ¹Synthetic ²Isolate



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 web-based Product Licence Application form for Compendial applications.

Use(s) or Purpose(s)

Refer to Tables 2.1 to 2.6. below.

Notes

- The recommended uses can be combined on the product label if from the same traditional or non-traditional system of medicine.
- The terms 'Helps' or 'Helps to' can be used interchangeably on the label.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Refer to Tables 2.1 to 2.7. below.

Note: Methods of preparation: Solvents allowed for the methods of preparation, Non-Standardized Extracts "Dry extract" and Non-Standardized Ethanolic Extracts "Dry extract" as part of this monograph are ethanol and/or water only, unless otherwise specified. For Non-Standardized Aqueous Extracts "Dry extract", water is the only solvent allowed.



Table 2.1. Cognitive function uses or purposes and associated daily doses for ingredients with nervine action

Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
(Traditionally) used in Herbal Medicine to help relieve restlessness and/or nervousness (nervine/calmative)	Anemone pulsatilla (Pasqueflower)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	0.03-0.6 grams dried herb top, per day
		Non-Standardized Aqueous Extracts (Dry extract, Decoction, Infusion)	0.1-0.9 grams dried herb top, per day
	Avena sativa (Oat)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	 0.6-20 grams dried seed, per day 3 grams dried herb top, per day
	<i>Nepeta cataria</i> (Catnip)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	1.2-12 grams dried herb top, per day
	Panax quinquefolius (American ginseng)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.5-12 grams dried root, per day
	<i>Tilia cordata</i> (Small-leaf linden)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	1.5-12 grams dried flower, per day
	<i>Tilia platyphyllos</i> (Large-leaf linden)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	1.5-12 grams dried flower, per day
	<i>Tilia x europaea</i> (European Linden)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	1.5-12 grams dried flower, per day
	<i>Turnera diffusa</i> (Damiana)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.5-4 grams dried leaf/leaf and stem, per day



Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
(Traditionally) used in Herbal Medicine to help relieve restlessness and/or nervousness (nervine/calmative)	<i>Hypericum</i> <i>perforatum</i> (St. John's wort)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	2-12.6 grams dried herb top, per day; Not to exceed 4.2 grams per single dose
Used in Herbal Medicine to help relieve restlessness and/or nervousness (nervine/calmative) AND/OR (Used in Herbal Medicine to) help(s) relieve sleep disturbances associated with mood imbalance		Standardized Extracts (Dry extract)	600-1800 milligrams of dried herb top extract, per day, standardized to 3-6% hyperforin and/or 0.12- 0.28% hypericin; Not to exceed 600 milligrams of extract per single dose
Helps (to) relieve sleep disturbances associated with mood imbalance	L-5- Hydroxytryptophan (L-5-HTP)	Isolate	100-200 milligrams, per day
(Traditionally) used in Herbal Medicine to help relieve restlessness and/or nervousness (which helps to promote sleep)	<i>Matricaria</i> <i>chamomilla</i> (German chamomile)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	1.5-24 grams dried flower, per day
(nervine/calmative)	<i>Melissa officinalis</i> (Lemon balm)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.4-13.5 grams dried herb top, per day
	Scutellaria lateriflora (Skullcap)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	0.25-12 grams dried herb top, per day
		Non-Standardized Aqueous Extracts (Dry extract, Decoction, Infusion)	3-12 grams dried herb top, per day
	Stachys officinalis (Wood betony)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	2-4 grams dried herb top, per day
Traditionally used in Ayurveda to balance aggravated Vata (nervine) AND/OR Traditionally used in Ayurveda to help relieve restlessness and/or	Withania somnifera (Ashwagandha)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	2-6 grams dried root, per day



Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
nervousness (which helps			
to promote sleep).			

¹References consulted for the uses or purposes: Sutanto et al. 2024; ESCOP 2009; Bradley 2006; Bone 2003; Hoffman 2003; Barnes et al. 2002; Kapoor 2001; Blumenthal et al. 2000; Upton 2000; Wheatley 1999; Poldinger et al. 1991; Williamson et al. 1988; Ellingwood 1983; Felter and Lloyd 1983; Soulairac and Lambinet 1977; Grieve 1971.

²References consulted for the doses: Sutanto et al. 2024; CNF 2023; EMA 2008; Anghelescu et al. 2006; Bone 2003; Hoffman 2003; API 2001; Kapoor 2001; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; BHP 1983; Ellingwood 1983; Felter and Lloyd 1983; Soulairac and Lambinet 1977; Remington and Wood 1918; BPC 1911.

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	Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
	(Traditionally) used in Herbal Medicine as a sleep aid (during times of mental stress). AND/OR	<i>Eschscholzia</i> <i>californica</i> (California poppy)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.2-3 grams dried herb top, per day
	(Traditionally) used in Herbal Medicine to help relieve restlessness and/or nervousness (calmative).	<i>Humulus lupulus</i> (Hops)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.5-6 grams dried strobile, per day
		Passiflora incarnata (Passionflower)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	0.25-8 grams dried herb top, per day
			Non-Standardized Aqueous Extracts (Dry extract, Decoction, Infusion)	1-8 grams dried herb top, per day
	(Traditionally used in Herbal Medicine as a) sleep aid/(to) help(s) to promote sleep. AND/OR	Valeriana officinalis (Valerian)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.3-12 grams dried root/root and rhizome, per day; Not to exceed 3.6 grams per single dose
	sleep. AND/OR (Traditionally) used in Herbal Medicine to relieve restlessness and/or nervousness (calmative)		Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.3-12 grams of dried root/root and rhizome, per day ³ ; Not to exceed 3.6 grams per single dose and: 0.05-0.90% valerenic acid

Table 2.2. Cognitive function uses or purposes and associated daily doses for ingredients with sedative (soporific) action

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Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
			OR 0.10-0.90% sesquiterpenic acids

¹References consulted for the uses or purposes: Williamson et al. 1988; refer to respective single ingredient monographs.

²References consulted for the doses: Williamson et al. 1988; refer to respective single ingredient monographs.

³Note: For Valerian extracts standardized to valerenic acid or sesquiterpenic acids, the quantity dried equivalent and the extract ratio must be provided.

Table 2.3. Cognitive	e function uses or	purposes and as	ssociated daily of	doses for ingred	ients with
cognitive support ac	ction				

Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
Helps support cognitive/brain	Acetylcarnitine	N/A	1.5-4 grams, per day
neatin/Tunction.	Bacopa monnieri (Bacopa)	Standardized Extracts (Dry extract)	300 milligrams dried whole plant/herb top extract, per day, standardized to 40-55% bacosides
	Cod liver oil	Standardized fixed oil	18 years: 0.77-4 grams Cod liver oil, per day And 150-1,360 milligrams EPA + DHA including at least 100 milligrams DHA, per day And 138-2,800 micrograms RAE (vitamin A), per day And 1.15-23.12 micrograms vitamin D ₃ , per day



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Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
			19 years and older: 0.77-4 grams Cod liver oil, per day And 150-1,360 milligrams EPA + DHA including at least 100 milligrams DHA, per day And 138-3,000 micrograms RAE (Vitamin A), per day And 1.15-25 micrograms Vitamin D ₃ , per day
	L-alpha- Glycerophosphoryl choline (Choline alfoscerate)	N/A	1.2 grams, per day
	Fish oil	Standardized fixed oil	150-5,000 milligrams EPA and DHA including at least 100 milligrams DHA, per day ³
	Phosphatidylserine	N/A	300 milligrams, per day
	Schizochytrium oil	Standardized fixed oil	200-2,000 milligrams DHA, per day
Helps (to) support memory	<i>Bacopa monnieri</i> (Bacopa)	Standardized Extracts (Dry extract)	300 milligrams dried whole plant/herb top extract, per day, standardized to 40- 55% bacosides
Traditionally used in Ayurveda for memory enhancement	<i>Bacopa monnieri</i> (Bacopa)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1-6.5 grams dried whole plant/herb top, per day
	Withania somnifera (Ashwagandha)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	2-6 grams dried root, per day
Helps (to) improve sustained attention.	Citicoline	N/A	250-1000 milligrams per day; not to exceed 500 milligrams per single dose



Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
Helps (to) support cognitive health and/or brain function in older adults.		N/A	500-1000 milligrams per day; not to exceed 500 milligrams per single dose
Used in Herbal Medicine to help improve mental performance after periods of mental exertion	<i>Eleutherococcus</i> <i>senticosus</i> (Eleuthero)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	0.91-6 grams dried root, per day
Helps (to) enhance cognitive function and/or memory in adults	<i>Ginkgo biloba</i> (Ginkgo)	Standardized Extracts (Dry extract)	80-240 milligrams of extract, per day (50:1; quantity crude equivalent 4 - 12 g of dried leaves, per day) providing at least 80 milligrams of extract per single dose and standardized to: 22-27% flavonoid glycosides And 5-7% terpene lactones
(Used in Herbal Medicine to) help(s) support cognitive function and/or reduce mental fatigue (in cases of mental stress)	Panax ginseng (Panax ginseng)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion)	0.5-9 grams dried root/ rootlet, per day
Helps support cognition		Standardized Extracts (Dry extract)	200-600 milligrams of extract, per day; standardized to 4-7% total ginsenosides; Not to exceed a quantity crude equivalent of 9 grams of dried root/rootlet, per day
(Used in Herbal Medicine) (to) help(s) support cognitive function (such as	<i>Rhodiola rosea</i> (Rhodiola)	Tincture	1.2-1.8 grams of dried root/root and rhizome, per day
stamina)		Standardized Extracts (Dry extract)	144-680 milligrams of dried root/root and rhizome extract, per day; Not to exceed 200 milligrams per single dose and: 0.8-3% salidroside And/Or 1-6% rosavins



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Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
Helps to decrease cognitive fatigue due to physically stressful situations (e.g. extended wakefulness, exposure to cold, excessive noise).	L-Tyrosine	N/A	10-20 grams, per day; Not to exceed 10 grams per single dose

¹References consulted for the uses or purposes: Nakazaki et al. 2021; McGlade et al. 2015, 2012; Morgan and Stevens 2010; Yurko-Mauro et al. 2010; Barbhaiya et al. 2008; Calabrese et al. 2008; Malaguanera et al. 2008; Stough et al. 2008; Raghav et al. 2006; Murthy 2004; De Jesus Moreno Moreno 2003; Roodenrys et al. 2002; API 2001; Parnetti et al. 2001; Stough et al. 2001; Thal et al. 2000; Upton 2000; Neri et al. 1995; Barbagallo et al. 1994; Pettegrewet al. 1994; Parnetti et al. 1993; Sano et al. 1992; Canal et al. 1991; Spagnoli et al. 1991.

²References consulted for the doses : Nakazaki et al. 2021; McGlade et al. 2015, 2012; Cotroneo et al. 2013; EFSA 2013; Jensen et al. 2010; Morgan and Stevens 2010; Quinn et al. 2010; Yurko-Mauro et al. 2010; Calabrese et al. 2008; Malaguanera et al. 2008; Mahoney et al. 2007; Bone 2003; De Jesus Moreno Moreno 2003; API 2001; Kapoor 2001; Parnetti et al. 2001; Stough et al. 2001; Thal et al. 2000; Barbagallo et al. 1994; Pettegrewet al. 1994; Parnetti et al. 1993; Sano et al. 1992; Canal et al. 1991; Spagnoli et al. 1991. ³For fish oil including species of Gadidae as a source material, the vitamin A and D content should be tested to ensure that the daily maximum amounts meet the Multi-Vitamin/Mineral Supplements monograph for each age group.

Uses or Purposes ¹	Medicinal Ingredient	Methods of preparation	Doses/day ²
Helps (temporarily) (to) promote alertness and wakefulness, and (to) enhance cognitive	1,3,7- Trimethylxanthine (Caffeine)	N/A	100-400 milligrams, per day and 100-200 milligrams per single dose
performance AND/OR Helps (temporarily) (to) relieve/reduce fatigue/tiredness AND/OR Helps (temporarily) (to) support/promote mental sharpness/alertness	<i>Ilex paraguariensis</i> (Yerba mate)	Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)	Extract standardized to caffeine corresponding to a maximum Quantity Crude Equivalent of 6 grams dried leaf, per day; not exceeding 150 milligrams caffeine per day; and providing 100- 150 milligrams caffeine per single dose
	<i>Paullinia cupana</i> (Guarana)	Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	Extract standardized to caffeine corresponding to a maximum Quantity Crude Equivalent of 3 grams dried seed per day and not exceeding 200

Table 2.4. Cognitive function uses or purposes and associated daily doses for caffeine and ingredients containing caffeine

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Uses or Purposes ¹	Medicinal Ingredient s	Methods of preparation	Doses/day ²
			milligrams caffeine per day; and providing 100- 200 milligrams caffeine per single dose
Used in Herbal Medicine to help temporarily promote alertness and wakefulness, and to enhance cognitive performance	Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	Extract standardized to caffeine corresponding to a Quantity Crude Equivalent of 3-6 grams dried leaf, per day and not exceeding 150 milligrams caffeine per day	
		Standardized Aqueous Extracts (Dry extract, Decoction, Infusion)	Extract standardized to caffeine corresponding to a Quantity Crude Equivalent of 2-6 grams dried leaf, per day and not exceeding 150 milligrams caffeine per day
	Paullinia cupana (Guarana)	Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	Extract standardized to caffeine corresponding to a Quantity Crude Equivalent of 1-3 grams dried seed, per day and not exceeding 200 milligrams caffeine per day

¹References consulted for the uses or purposes: EMA 2013; EMA 2010; ESCOP 2009; Bradley 2006; Christopher et al. 2005; Kennedy al. 2004; Taylor 2003; Barnes et al. 2002; Kamimori et al. 2000; Zwyghuizen- Doorenbos et al. 1990.

²References consulted for the doses: Health Canada 2018; EMA 2013; Health Canada 2012; EMA 2010; ESCOP 2009; Bradley 2006; Taylor 2003.

Table 2.5. Cognitive function uses or purposes and associated daily doses for ingredients with relaxation action

Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
Helps (to) temporarily promote relaxation	4-Aminobutanoic acid (GABA)	N/A	50-3,000 milligrams, per day; Not to exceed 750 milligrams per single dose
	L-Theanine	N/A	200-250 milligrams, per day

¹References consulted for the uses or purposes: Kanehira et al. 2011; Abdou et al. 2006.

²References consulted for the doses: Kanehira et al. 2011; Powers et al. 2007; Yamakoshi et al. 2006.



Table 2.6. Cognitive function uses or purposes and associated daily doses for ingredients with adaptogen action

Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress over	Asparagus racemosus (Shatavari)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	2-6 grams dried root, per day
time (e.g. in case of mental and physical fatigue related to stress)	Astragalus membranaceus (Astragalus)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	2-4.8 grams dried root, per day
	<i>Eleutherococcus</i> <i>senticosus</i> (Eleuthero)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1-6 grams dried root/ root and rhizome, per day
		Non-Standardized Aqueous Extracts (Dry extract, Decoction, Infusion)	2-3 grams dried root/ root and rhizome, per day
	<i>Ganoderma lucidum</i> (Reishi)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.5-6 grams dried cultured mycelium/ fruiting body/ mycelium, per day
		Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.5-6 grams of dried cultured mycelium/ fruiting body/ mycelium, per day and not to exceed 40 % polysaccharides
		Decoction, Decoction concentrate	3-15 grams dried cultured mycelium/ fruiting body/ mycelium, per day
		Decoction Standardized, Decoction concentrate Standardized	3-15 grams dried cultured mycelium/ fruiting body/ mycelium, per day and not to exceed 40 % polysaccharides
	<i>Glycyrrhiza glabra</i> (Licorice)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	0.6-6 grams dried root/ root and stolon, per day
	Ocimum tenuiflorum (Holy basil)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	2-3 grams dried leaf, per day
		Non-Standardized	4.2-28 grams dried leaf,

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Canada



Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
		Aqueous Extracts (Dry extract, Decoction, Infusion)	per day
	Panax ginseng (Panax ginseng)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid Extract, Decoction, Infusion)	0.5-9 grams dried root/ rootlet, per day
		Standardized Extracts (Dry extract)	200-600 milligrams of extract, per day; standardized to 4-7% total ginsenosides; Not to exceed a quantity crude equivalent of 9 grams dried root/rootlet, per day
	Panax quinquefolius (American ginseng)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1-3 grams dried root, per day
		Non- Standardized Aqueous Extracts (Dry extract, Decoction, Infusion)	6-9 grams dried root, per day; Not to exceed 3 g per single dose
	Rhodiola rosea (Rhodiola)	Non-Standardized Ethanolic Extracts (Dry extract)	144-400 milligrams of dry extract and a quantity crude equivalent of 216-2,000 milligrams of dried root/root and rhizome, per day; Not to exceed 200 milligrams of dry extract and a QCE of 1 gram of dried root/root and rhizome, per single dose
		Tincture	1.2-1.8 grams of dried root/root and rhizome, per day
		Standardized Extracts (Dry extract)	144-680 milligrams of dried root/root and rhizome extract, per day; Not to exceed 200 milligrams per single dose and: 0.8 - 3% salidroside

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Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
			And/Or 1 - 6% rosavins
	Schisandra chinensis (Schisandra)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	1.2-6 grams dried fruit, per day
		Non-Standardized Aqueous Extracts (Dry extract, Decoction, Infusion)	1.5-6 grams dried fruit, per day
	<i>Tinospora cordifolia</i> (Guduchi)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	0.9-3 grams dried stem, per day
		Decoction, Decoction concentrate	20-30 grams dried stem, per day
	Withania somnifera (Ashwagandha)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	2.5-6.5 grams dried root/whole plant, per day
(Used as an adaptogen) (to) help(s) (to) temporarily relieve symptoms of stress (such as mental fatigue and sensation of weakness)	<i>Rhodiola rosea</i> (Rhodiola)	Non-Standardized Ethanolic Extracts (Dry extract)	144-400 milligrams dry extract and a Quantity Crude Equivalent (QCE) of 216-2,000 milligrams of dried root/root and rhizome, per day; Not to exceed 200 milligrams of extract and a QCE of 1 gram of dried root/root and rhizome, per single dose
		Tincture	1.2-1.8 grams of dried root/root and rhizome, per day
		Standardized Extracts (Dry extract)	144-680 milligrams of dried root/root and rhizome extract, per day; Not to exceed 200 milligrams per single dose and: 0.8 - 3% salidroside And/Or 1 - 6% rosavins
Traditionally used in Ayurveda as Rasayana (rejuvenative tonic)	Asparagus racemosus (Shatavari)	Dry, Powder, Non- Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract)	3-6 grams dried root, per day

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Uses or Purposes ¹	Medicinal Ingredients	Methods of preparation	Doses/day ²
	Withania somnifera (Ashwagandha)	Dry, Powder, Non- Standardized Extracts (Dry extract, Tincture, Fluid extract,	2-6 grams dried root, per day
		Decoction, Infusion)	

¹References consulted for the uses or purposes: Upton 2012; Winston and Maimes 2007; Mills and Bone 2005; API 2004; WHO 2004; Bone 2003; Hoffman 2003; Thomsen 2002; Williamson 2002; API 2001; Blumenthal et al. 2000; Upton 2000, 1999; WHO 1999; Bradley 1992.

²References consulted for the doses: Upton 2012; Winston and Maimes 2007; Mills and Bone 2005; API 2004, 2001; WHO 2004; Bone 2003; Hoffman 2003; Thomsen 2002; Williamson 2002; Kapoor 2001; Blumenthal et al. 2000; Upton 1999; WHO 1999; Bradley 1992.

Table 2.7. Maximum daily doses for complementary ingredients with no associated recommended use

Medicinal Ingredients	Methods of preparation	Doses/day ¹
<i>Huperzia serrata</i> (Toothed club-moss)	Standardized extracts (Dry extract)	Up to 20 milligrams extract standardized to huperzine A, per day; Not to exceed 1% huperzine A potency
Huperzine A	N/A	Up to 200 micrograms, per day
Theacrine	N/A	Up to 300 milligrams, per day
Theobromine	N/A	Up to 850 milligrams, per day

¹References consulted for the doses: Clewell et al. 2016; Taylor et al. 2016; Neufingerl et al. 2013; Ma et al. 2007; Sun et al. 1999.

Direction(s) for use

See Table 5 below.

Combination rules and restrictions

All medicinal ingredients included in this monograph may be combined across all groups, with the following restrictions:

Use or Purpose Restrictions

- A use or purpose statement is only acceptable if at least one medicinal ingredient associated with that statement is present at a dose at or above the minimum daily dose listed in Tables 2.1 to 2.6.
- Medicinal ingredients which do not meet the minimum daily dose for a use or purpose statement will be considered as acceptable complementary medicinal ingredients in product formulations.
- For multi-ingredient products making at least one claim based on traditional use:



- To prevent the product from being represented as a "traditional medicine," any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g. German chamomile is traditionally used in Herbal Medicine to help relieve restlessness and/or nervousness. Ashwagandha is traditionally used in Ayurveda to balance aggravated Vata).
- When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

Rules for sedative (soporific) ingredients (table 2.2)

If sedative ingredients (table 2.2) are combined, the sum of the percentages of the maximum daily reference dose must not exceed 120%, for all sedative ingredients in the product (including sedative ingredients supported by other NNHPD monographs such as melatonin). Note that no single ingredient can exceed 100% of its maximum daily reference dose. Please see Table 3 below for a calculation example.

Additive Indication	e.g. Used in Herbal M	edicine as a sleep aid	
Medicinal Ingredients	Maximum Daily Recommended Dose on PLA form	Maximum Daily Monograph Reference Dose	Percentage of the Maximum Daily Reference Dose (%)
<i>Eschscholzia</i> <i>californica</i> (California poppy)	0.5 g	3 g	0.5/3 = 16.67%
Humulus lupulus (Hops)	4 g	6 g	4/6 = 66.66%
Passiflora incarnata (Passionflower)	0.5 g	8 g	0.5/8 = 6.25%
Sum of Percentages			89.6%

Table 3. Combination Table to assess Safety of Sedative/Soporific Ingredients

The calculations are performed as follows:

• Percentage of the Maximum Daily Reference Dose = [(Maximum Daily Recommended Dose on PLA form) / (Maximum Daily Monograph Reference Dose)] x 100%

Safety assessment - Sum of Percentages:

• In the example above, the sum of Percentages of the Maximum Daily Reference Dose is 89.6%, which is less than 120%. Safety of the combination of ingredients is therefore supported by the monograph.



Rules for Caffeine

- If a product contains caffeine from any source, it cannot contain a sedative at a therapeutic dose (table 2.2) and nervine/sedative/relaxation claims (tables 2.1, 2.2 & 2.5) are not permitted.
- Products containing a total amount of caffeine per day that meets the minimum therapeutic dose (100 mg/day) must indicate a use or purpose associated with caffeine.
- Products containing caffeine either synthetic, isolated or from plant materials must not:
 - indicate any uses or purpose related to healthy blood pressure or cardiovascular health at any dose (except if supported by a monograph for a medicinal ingredient providing caffeine such as green coffee bean extract).
 - indicate any uses or purpose related to the maintenance/support of good/general health at a daily dose of 40 mg or more total caffeine from all sources.
- The maximum amount of total caffeine permitted from all ingredients in the product is 400 mg/day, and 200 mg per single dose.
- If the total amount of caffeine provided by the combination of ingredients in the product (e.g. Yerba mate and Guarana) is equal to or higher than 40 mg per day, risk statements from the NNHPD Caffeine Monograph are required. Please see Table 5 below.
- Additional synthetic caffeine added to Guarana and/or Yerba mate extracts must be represented as a separate medicinal ingredient.
- When caffeine (from any source) is combined with theacrine and/or theobromine, the sum of the percentages of the maximum daily/single reference dose must not exceed 120% for these ingredients. Note that no single ingredient can exceed 100% of its maximum daily/single reference dose. Please see table 4 below.

Additive Effect	Ingredients which may have an impact on heart rate and/or blood pressure		
Medicinal Ingredients	Maximum Daily/ Single Recommended Dose on PLA form	Maximum Daily/ Single Monograph Reference Dose	Percentage of the Maximum Daily/ Single Reference Dose (%)
Caffeine	100 mg	200 mg per single dose/400 mg per day	100/200 = 50% (single dose) 100/400 = 25% (day)
Theacrine	120 mg	300 mg	120/300 = 40%
Theobromine	50 mg	850 mg	50/850 = 5.9%
Sum of Percentages			95.9% per single dose/ 70.9% per day

Table 4. Combination Table to assess safety of ingredients with a caution for cardiovascular and/or blood pressure conditions.

See table 3 above for an example of calculations. In this example, the sum of Percentages of the Maximum Monograph Reference Single Dose is 95.9%, which is less than 120%. Safety of the combination of ingredients is therefore supported by the monograph.

Rules for Huperzine A

When combining *Huperzia serrata* extract and Huperzine A (isolate or synthetic), the total quantity of Huperzine A provided by the product cannot exceed 200 micrograms per day.

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Duration(s) of use

See Table 5 below.

Risk information

Consult Table 5 for appropriate statements related to each medicinal ingredient. The medicinal ingredients in Table 5 are associated with the required numbered statements below.

1. As per the respective NNHPD monograph.

Duration(s) of Use

- 2. Products providing Huperzia serrata, Huperzine A, 300 mg or more GABA per day, or over 150 mg Theobromine per day: Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks.
- 3. *Products providing 101 to 300 mg/day Theacrine:* Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 8 weeks.

Caution(s) and warning(s)

- 4. Ask a health care practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen.
- 5. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are pregnant or breastfeeding.
- 6. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are pregnant.
- 7. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are breastfeeding.
- 8. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have a urinary tract disorder and/or kidney disease.
- 9. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have kidney disease and/or a seizure disorder.
- 10. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have high blood pressure or glaucoma.
- 11. Products providing Huperzia serrata, huperzine A, or over 150 mg/day theobromine: Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have a cardiovascular or blood pressure condition.
- 12. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are taking medications which affect acetylcholine levels (cholinergic or anticholinergic drugs).
- 13. Ask a health care practitioner/health care provider/health careprofessional/doctor/ physician before use if you are taking dopaminergic or cholinergic drugs.
- 14. Products making a sustained attention claim: Ask a health care practitioner/health care provider/health careprofessional/doctor/ physician before use if you have an attention deficit disorder with or without hyperactivity (ADD or ADHD).
- 15. When using this product exercise caution if you drive or use machinery as you may experience drowsiness.
- 16. Products providing 300 mg or more GABA per day: When using this product avoid taking Cognitive Functions Products Page 25 of 41





with alcohol.

Contraindication(s)

- 17. Do not use if you are pregnant orbreastfeeding.
- 18. **Do not use** if you are pregnant.
- 19. Do not use if you have gastrointestinal irritation.

Known adverse reaction(s)

- 20. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience dizziness, unusual muscle cramping, agitation, gastrointestinal symptoms such as nausea, vomiting, diarrhea or excessive salivation.
- 21. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if hypersensitivity/allergy occurs.
- 22. Stop use if you experience severe stomach and/or intestinal irritation.
- 23. When using this product you may experience gastrointestinal discomfort/disturbances.
- 24. When using this product you may experience headaches or gastrointestinal disturbances.
- 25. When using this product (a) diuretic effect may occur.

Medicinal Ingredients	Risk Information	Durations of Use	Directions for use
1,3,7-Trimethylxanthine (Caffeine)	1		1
4-Aminobutanoic acid (GABA)	5,16	2	
Acetyl-L-Carnitine (Acetylcarnitine)	5,9,23		
Anemone pulsatilla (Pasqueflower)	4,8,17,19,22		
Asparagus racemosus (Shatavari)	6		
Astragalus membranaceus (Astragalus)	1		
Avena sativa (Oat)	4		
Bacopa monnieri (Bacopa)	5,23		
Citicoline	5,13,14,24		
Cod liver oil	1		
Eleutherococcus senticosus (Eleuthero)	1	1	
Eschscholzia californica (California	1		1
poppy)			
Fish oil	1		
Ganoderma lucidum (Reishi)	1		1
Ginkgo biloba (Ginkgo)	1	1	
Glycyrrhiza glabra (Licorice)	1	1	
Humulus lupulus (Hops)	1		1
Huperzia serrata; Huperzine A	11,12,17,20	2	
Hypericum perforatum (St. John's wort)	1	1	
Ilex paraguariensis (Yerba mate)	5,10,21,25		
L-5-Hydroxytryptophan (L-5-HTP)	1	1	1

Table 5. Risk information, durations of use, and directions for use associated with medicinal ingredients

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Medicinal Ingredients	Risk Information	Durations	Directions
L-alpha-Glycerophosphorylcholine	5	01 0 50	101 use
(Choline alfoscerate)	5		
L-Theanine	1		
L-Tyrosine	1	1	1
Matricaria chamomilla (German	1		
chamomile)			
Melissa officinalis (Lemon balm)	1		
Nepeta cataria (Catnip)	1		
Ocimum tenuiflorum (Holy basil)	1		
Panax ginseng (Asian ginseng)	1	1	
Panax quinquefolius (American ginseng)	1		
Passiflora incarnata (Passionflower)	1		1
Paullinia cupana (Guarana)	5,10,21,25		
Phosphatidylserine	1		
Rhodiola rosea (Rhodiola)	1		
Schisandra chinensis (Schisandra)	7,18		
Scutellaria lateriflora (Skullcap)	1		
Stachys officinalis (Wood Betony)	4,5,15		
Theacrine	5,10	3	
Theobromine	5,11,23	2	
Tilia cordata (Small-leaf linden)	1		
Tilia platyphyllos (Large-leaf linden)	1		
Tilia x europaea (European linden)	1		
Tinospora cordifolia (Guduchi)	5		
Turnera diffusa (Damiana)	4,7,18		
Valeriana officinalis (Valerian)	1		1
Withania somnifera (Ashwagandha)	1		
Combination of ingredients resulting in a total caffeine content of 40 mg/day or more (e.g. Yerba mate and Guarana extracts)	as per the caffeine monograph		as per the caffeine monograph

References: Nakazaki et al. 2021; Clewell et al. 2016; Taylor et al. 2016; Kuhman et al. 2015, McGlade et al. 2015, Morasch et al. 2015, Baggott et al. 2013, Cotroneo et al. 2013; EFSA 2013; EMA 2013; Gardner and McGuffin 2013, Neufingerl et al. 2013, Yang et al. 2013, McGlade et al. 2012, Fiebich et al. 2011; AMR 2010; Morgan and Stevens 2010; Okun et al. 2010, Van den Bogaard et al. 2010; ESCOP 2009; Wang et al. 2009; Calabrese et al. 2008; CPS 2008; Li et al. 2006; Mills et al. 2006; Shils et al. 2007; Powers et al. 2007; Bain et al.2006; Bradley 2006; Bui et al. 2006; Mills et al. 2006; Shils et al. 2006; Turner et al. 2006; Bouchard et al. 2005; Chandrasekaran et al. 2005; Haller et al. 2005; Noordzij et al. 2005; Nathan et al. 2004; Bone 2003; Zangara 2003; Avisar et al. 2002; Barnes et al. 2002; Berardi et al. 2002; Thomsen 2002; Brinker 2001; Nathan et al. 2001; Stough et al. 2001; Arya et al. 2000; Pepping 2000; Vahedi et al. 2000; Jee et al. 1999; Sun et al. 1999; Mester et al. 1995; Xu et al. 1995, Bradley 1992; Zimmerman 1992; Creighton and Stanton 1990; Rai et al. 1990; Jefferson 1988.



Non-medicinal ingredients

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

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

Products containing Cod liver oil, Fish oil or Schizochytrium oil

(except when encapsulated)

Refrigerate after opening (Senanayake and Fichtali 2006; Wille and Gonus 1989).

(information for industry; not for labelling)

To be packaged in airtight container, protected from light (Ph.Eur. 2023; USP-NF 2023).

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.
- For the following ingredients, please see the respective NNHPD monograph for additional quality requirements: Astragalus, American ginseng, Cod liver oil, Eleuthero, Fish oil, German chamomile-Oral, Gingko biloba, Hops, Licorice, Panax ginseng, St John's wort, L- Tyrosine, L-Theanine, Valerian.



EXAMPLES OF PRODUCT FACTS:

Consult the Guidance Document, <u>Labelling of Natural Health Products</u> for more details.

Product Facts	
Medicinal ingredients in each capsule	
Eschscholzia californica (California poppy – herb top)	XX mg
Melissa officinalis (Lemon balm – herb top)	XX mg
L-Theanine (Camellia sinensis – leaf)	XX mg
Passiflora incarnata (Passionflower) (X:1 extract)	XX mg
Equivalent to YY g of dried herb top	-
Uses	
• Lemon balm is traditionally used in Herbal Medicine to help relieve restlessness and nerv	ousness
which helps to promote sleep.	
• Used in Herbal Medicine as a sleep aid.	
Helps to temporarily promote relaxation.	
Warnings	
If applicable ¹ : Allergens: food allergen, gluten (gluten source), sulphites	
Contains aspartame	
Do not use if you are pregnant.	
Ask a health care practitioner before use if you are breastfeeding.	
When using this product • avoid taking with alcohol or products that cause drowsiness or	with
analgesic properties • exercise caution if you drive or use machinery as you may experience	e
drowsiness.	
Stop use if hypersensitivity/allergy occurs.	
Ask a health care practitioner if • sleeplessness persists for more than 4 weeks (chronic i	nsomnia)
• symptoms persist or worsen (nervousness).	
Directions	
Adults 18 years and older: • Take X capsule(s), X time(s) a day • Take 1 hour before bedt	me, as
needed.	
Other information	
(Add storage information)	
Non-medicinal ingredients	
List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	
¹ This section can be removed from the table if the product contains no allergen or aspartame	



Product Facts
Medicinal ingredients in each capsule
Panax quinquefolius (American ginseng – root) XX mg
Bacopa monnieri (Bacopa) – herb top extract XX mg
Providing 50% bacosides
Fish oil (Atlantic salmon, sardine, tuna – whole) XX mg
Providing • Eicosapentaenoic acid (EPA) YY mg • Docosahexaenoic acid (DHA) ZZ mg
Uses
Helps support cognitive function.
• Helps support memory.
• Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress over time.
Warnings
If applicable ¹ : Allergens: food allergen, gluten (gluten source), sulphites
Contains aspartame
Ask a health care practitioner before use if • you are pregnant or breastfeeding • you are taking
blood thinners or digoxin • you have diabetes.
When using this product you may experience gastrointestinal discomfort.
Ask a health care practitioner if symptoms persist or worsen.
Directions
Adults 18 years and older: • Take X capsule(s), X time(s) a day.
Other information
(Add storage information)
Non-medicinal ingredients
List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

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