

Rhodiola - Rhodiola rosea

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RHODIOLA - RHODIOLA ROSEA Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 25 KB) 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 ingredient. 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. Date January 27, 2023 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Rhodiola rosea Hong jing tian King's-crown Rhodiola Roseroot Rhodiola rosea Root Root and rhizome Dry References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000; Source information: EMA 2012, Winston and Maimes 2007. 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) (Used in Herbal Medicine) (as an adaptogen) (to) help(s) (to) temporary relieve symptoms of stress (such as mental fatigue and sensation of weakness) (EMA 2012; Olsson et al. 2009; Winston and Maimes 2007; Pizzorno and Murray 2006; Hoffman 2003). Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress (e.g. in case of mental and physical fatigue related to stress) (EMA 2012; Olsson et al. 2009; Winston and Maimes 2007; Pizzorno and Murray 2006; Hoffman 2003). (Used in Herbal Medicine) (to) help(s) support cognitive function (such as mental focus and mental stamina) (Olsson et al. 2009; Winston and Maimes 2007). Source of/Provides antioxidants (Skarpaniska-Stejnborn et al. 2009; Winston and Maimes 2007; Kim et al. 2006). The following combined use(s) or purpose(s) is/are also acceptable: (Used in Herbal Medicine) (to) help(s) support cognitive function (such as mental focus and mental stamina) and (as an adaptogen) (to) help(s) (to) temporary relieve symptoms of stress (EMA 2012; Olsson et al. 2009; Winston and Maimes 2007; Pizzorno and Murray 2006; Hoffman 2003). Dose(s) Subpopulation(s) Adults 18 years and older (EMA 2012) Quantity(ies) Antioxidant Methods of preparation: Standardized extracts (Dry extract) Not to exceed 680 milligrams of extract, per day and 200 milligrams, per single dose (EMA 2012; Darbinyan et al. 2007; Pizzorno and Murray 2006) and: 0.8 - 3% salidroside (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002); and/or: 1 - 6% rosavins (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002). Methods of preparation: Non-Standardized Ethanolic Extracts (Dry extract) Not to exceed 400 milligrams of dry extract and a quantity crude equivalent (QCE) of 2 grams 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 (EMA 2012). Method of preparation: Tincture Not to exceed 1.8 grams of dried root/root and rhizome, per day (Winston and Maimes 2007). Symptoms of Stress, Adaptogen and Cognitive Function Methods of preparation: Standardized extracts (Dry extract) 144 - 680 milligrams of extract, per day; Not to exceed 200 milligrams per single dose (EMA 2012; Darbinyan et al. 2007; Pizzorno and Murray 2006) and: 0.8 - 3% salidroside (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002); and/or 1 - 6% rosavins (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002). Method of preparation: Tincture 1.2 - 1.8 grams of dried root/root and rhizome, per day (Winston and Maimes 2007). Symptoms of Stress and Adaptogen Methods of preparation: Non-Standardized Ethanolic Extracts (Dry extract) 144 - 400 milligrams of 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 dry extract and a QCE of 1 gram of dried root/root and rhizome, per single dose (EMA 2012). Direction(s) for use Avoid taking before bedtime (Iovieno et al. 2011; Pizzorno and Murray 2006; Kelly 2001). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Consult a health care practitioner/health care

provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (EMA 2012). Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking antidepressant medication, hormone replacement therapy (HRT) or birth control medication (HC 2018; Iovieno et al. 2011; Olsson et al. 2009; Brown et al. 2002). Contraindication(s) Do not use this product if you have bipolar disorder or bipolar spectrum disorder (Iovieno et al. 2011; Winston and Maimes 2007; Brown et al. 2002). Known adverse reaction(s) Stop use if you experience irritability or insomnia (Pizzorno and Murray 2006; Kelly 2001). 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR). 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. References Cited Add your content...AU TGA 2008: Australian Therapeutic Goods Administration. Explanatory Statement: Therapeutic Goods (Listing) Notice 2008 (No. 4) *Rhodiola rosea*. [Internet]. Symonston (AU): Australian Government Department of Health and Ageing, Therapeutic Goods Administration. [Accessed 2018 December 17]. Available from: <http://www.comlaw.gov.au/Details/F2008L02820> Brown RP, Gerbarg PL, Ramazanov Z. *Rhodiola rosea*: A Phytomedicinal Overview. *HerbalGram* 2002;56:40-52. Darbinyan V, Aslanyan G, Amroyan E, Gabrielyan E, Malmstrom C, Panossian A. 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[Accessed 2018 December 17]. Available from : <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html> Hoffmann D. *Medical Herbalism: The Science and Practice of Herbal Medicine*. Rochester (VT): Healing Arts Press; 2003. Iovieno, N., Dalton, ED., Fava, M., Mischoulon, D. Second-tier natural antidepressants: review and critique. *Journal of Affective Disorders* 2011; 130(3): 343-357 Kelly GS. *Rhodiola rosea*: A Possible Plant Adaptogen. *Alternative Medicine Review* 2001; 6(3): 293-302 Kim SH, Hyun SH, Choung SY. Antioxidant effects of *Cinnamomi assia* and *Rhodiola rosea* extracts in liver of diabetic mice. *Biofactors* 2006;26(3): 209-219 McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. *Herbs of Commerce*. 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000. Pizzorno JE, Murray MT, editors. *Textbook of Natural Medicine*. Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006. USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 December 17]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxonomydetail.aspx?id=31156> Winston D, Maimes S. *Adaptogens: Herbs for Strength, Stamina, and Stress Relief*. Rochester (VT): Healing Arts Press, 2007. References Reviewed Abidov M, Grachev S, Seifulla RD, Ziegenfuss TN. Extract of *Rhodiola rosea* radix reduces the level of C-reactive protein and creatinine kinase in the blood. *Bulletin of Experimental Biology and Medicine* 2004;138:63-64. Blomkvist J, Taube A, Larhammar D. Perspective on roseroot (*Rhodiola rosea*) studies. *Planta Medica* 2009;75:1187-1190. 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Acute *Rhodiola Rosea* Intake Can Improve Endurance Exercise Performance. *International Journal of Sport Nutrition and Exercise Metabolism* 2004;14:298-307. Edward D, Heufelder A, Zimmermann Z. Therapeutic Effects and Safety of *Rhodiola rosea* Extract WS® 1375 in Subjects with Life-stress Symptoms - Results of an Open-label Study. *Phytotherapy Research* 2012;26:1220-1225. Hung SK, Perry R, Ernst E. The effectiveness and efficacy of *Rhodiola rosea* L: A systematic review of randomized clinical trials. *Phytomedicine* 2011;18:235-244. Ishaque S, Shamseer L, Bukutu C, Vohra S. *Rhodiola rosea* for physical and mental fatigue:

a systematic review. *Complementary & Alternative Medicine* 2012;12:70-78. ITIS Regional 2011: Orrell T, custodian. ITIS Regional: The Integrated Taxonomic Information System (version Apr 2011). In: Bisby F, Roskov Y, Culham A, Orrell T, Nicolson D, Paglinawan L, Bailly N, Appeltans W, Kirk P, Bourgoin T, Baillargeon G, Ouvrard D, editors. *Species 2000 & ITIS Catalogue of Life, 2012 Annual Checklist*. DVD; Reading (GB): Species 2000; 2012. [Accessed 2012 November 30] Available from: <http://www.catalogueoflife.org/annual-checklist> Noreen EE, Buckley JG, Lewis SL, Brandauer J, Stuempfle KJ. The effects of an acute dose of *Rhodiola rosea* on endurance exercise performance. *Journal of Strength and Conditioning Association* 2013;27(3):839-847. Panossian A, Wilkman G, Sarris J. *Rosenroot (Rhodiola rosea): Traditional use, chemical composition, pharmacology and clinical efficacy*. *Phytomedicine* 2010;17:481-493. Parisi A, Tranchita E, Duranti G, Ciminelli E, Quaranta I, Ceci R, Cerulli C, Borriore P, Sabatini S. Effects of chronic *rhodiola rosea* supplementation on sport performance and antioxidant capacity in trained male: preliminary results. *The Journal of Sports Medicine and Physical Fitness* 2010;50:57-63. Peschel W, Prieto JM, Karkour C, Williamson EM. Effect of provenance, plant part and processing on extract profiles from cultivated European *Rhodiola rosea* L. for medicinal use. *Phytochemistry* 2013;86:92-102. Shevtsov VA, Zhulus BI, Shervarly VI, Vol'skij VB, Korovin YP, Khristich MP, Roslyakova NA, Wikman G. A randomized trial of two different doses of a SHR-5 *Rhodiola rosea* extract versus placebo and control of capacity for mental work. *Phytomedicine* 2003;10:95-105. Skarpanska-Stejnborn A, Pilaczynska-Szczesniak L, Basta P, Deskur-Smielecka E. The influence of supplementation with *Rhodiola rosea* L. extract on selected redox parameters in professional rowers. *International Journal of Sport Nutrition and Exercise Metabolism* 2009; 19(2): 186-199 Spasov AA, Wikman GK, Mandrikow VB, Mironova IA, Neumoin VV. A double-blind, placebo-controlled pilot study of the stimulating and adaptogenic effect of *Rhodiola rosea* SHR-5 extract on the fatigue of students caused by stress during an examination period with a repeated low-dose regimen. *Phytomedicine* 2000;7:85-89. Walker TB, Altobelli SA, Caprihan A, Robergs RA. Failure of *Rhodiola rosea* to alter skeletal muscle phosphate kinetics in trained men. *Metabolism* 2007;56(8):1111-1117. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).

DOSAGE FORM(S)

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.

DOSE(S)

Skarpanska-Stejnborn A, Pilaczynska-Szczesniak L, Basta P, Deskur-Smielecka E. The influence of supplementation with *Rhodiola rosea* L. extract on selected redox parameters in professional rowers. *International Journal of Sport Nutrition and Exercise Metabolism* 2009; 19(2): 186-199 Spasov AA, Wikman GK, Mandrikow VB, Mironova IA, Neumoin VV. A double-blind, placebo-controlled pilot study of the stimulating and adaptogenic effect of *Rhodiola rosea* SHR-5 extract on the fatigue of students caused by stress during an examination period with a repeated low-dose regimen. *Phytomedicine* 2000;7:85-89. Walker TB, Altobelli SA, Caprihan A, Robergs RA. Failure of *Rhodiola rosea* to alter skeletal muscle phosphate kinetics in trained men. *Metabolism* 2007;56(8):1111-1117.

RISK INFORMATION

Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (EMA 2012).Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking antidepressant medication, hormone replacement therapy (HRT) or birth control medication (HC 2018; Iovieno et al. 2011; Olsson et al. 2009; Brown et al. 2002). Contraindication(s) Do not use this product if you have bipolar disorder or bipolar spectrum disorder (Iovieno et al. 2011; Winston and Maimes 2007; Brown et al. 2002). Known adverse reaction(s) Stop use if you experience irritability or insomnia (Pizzorno and Murray 2006; Kelly 2001).

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 Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR).

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.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Rhodiola rosea	Hong jing tianKing's-crownRhodiolaRoseroot	Rhodiola rosea	RootRoot and rhizome	Dry