

NATURAL HEALTH PRODUCT

RHODIOLA – *RHODIOLA ROSEA*

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 the 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)
<i>Rhodiola rosea</i>	<ul style="list-style-type: none"> ▶ Hong jing tian ▶ King's-crown ▶ Rhodiola ▶ Roseroot 	<i>Rhodiola rosea</i>	<ul style="list-style-type: none"> ▶ 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 (Skarpanska-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

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. Clinical trial of *Rhodiola rosea* L. extract SHR-5 in the treatment of mild to moderate depression. *Nordic journal of psychiatry* 2007;61(5):343-348.

EMA 2012: 27 March 2012 EMA/HMPC/232091/2011 Committee on Herbal Medicinal Products (HMPC) Community herbal monograph on *Rhodiola rosea* L., rhizoma et radix Final. London (GB): European Medicines Agency, Science Medicines Health [Internet]. [Accessed 2018 December 17]. Available from: https://www.ema.europa.eu/documents/herbal-monograph/final-community-herbal-monograph-rhodiola-rosea_en.pdf

Felter HW. *The Eclectic Materia Medica, Pharmacology and Therapeutics*. Cincinnati (OH): John K. Scudder; 1922. [Internet]. Reprinted and abridged by Southwest School of Botanical Medicine; 2001. [Accessed 2018 December 17]. Available from: http://www.swsbm.com/FelterMM/Felters_Materia_Medica.pdf

HC 2018: Health Canada. Canada Vigilance Adverse Reaction Online Database. Ottawa (ON): Marketed Health Products Directorate, Health Canada. [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 5assia 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.

Brinker F. Final Updates and Additions for Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications. [Internet]. [Last update 2010 July 13; Accessed 2011 June 23]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

Brinker F. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

Bystritsky A, Kerwin L, Feusner JD. A pilot study of *Rhodiola rosea* (Rhodax®) for Generalized Anxiety Disorder (GAD). *The Journal of Alternative and Complementary Medicine* 2008;14:175-180.

Darbinyan V, Kteyan A, Panossian A, Gabrielian E, Wikman G, Wagner H. *Rhodiola rosea* in stress induced fatigue - a double blind cross-over study of a standardized extract SHR-5 with a repeated low-dose regimen on the mental performance of healthy physicians during night duty. *Phytomedicine* 2000;7:365-371.

De Bock K, Eijnde BO, Ramaekers M, Hespel P. 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, Borrione 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, Zholus 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.