

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 October 24, 2013

Proper name(s)

Rhodiola rosea L. (Crassulaceae) (USDA 2007; McGuffin et al. 2000)
(Synonym: *Sedum rosea* (L.) Scop. (USDA 2007; McGuffin et al. 2000))

Common name(s)

- ▶ Rhodiola (McGuffin et al. 2000)
- ▶ Roseroot (USDA 2007; McGuffin et al. 2000)

Source material(s)

- ▶ Root (Winston and Maimes 2007)
- ▶ Root and rhizome (EMA 2012)

Route(s) of administration

Oral

Dosage form(s)



- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s) Statement(s) to the effect of

- ▶ (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 2012a; 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).
- ▶ Provides antioxidants (Skarpanska-Stejnborn et al. 2009; Winston and Maimes 2007; Kim et al. 2006).

Dose(s) Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years) (EMA 2012)

Quantity(ies)

Symptoms of stress and cognitive function

Standardized extract:

144-680 mg extract per day, not to exceed 200 mg per single dose (EMA 2012; Darbinyan et al. 2007; Pizzorno and Murray 2006)

Potency:

- 0.8-3% salidroside (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002).
- 1-6% rosavins (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002).

Tincture:

1.2-1.8 g dried root/rhizome, per day [1:4; 4.8-7.2 ml] (Winston and Maimes 2007)

Symptoms of stress

Dry non-standardized extract:

144-400 mg dry extract, per day, not to exceed 200 mg per single dose [1.5-5:1, 67-70% ethanol v/v] (EMEA 2012).

Antioxidant



Standardized extract:

Up to 600 mg extract per day, not to exceed 200 mg per single dose (EMA 2012; Pizzorno and Murray 2006).

Potency:

- 0.8-3% salidroside (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002).
- 1-6% rosavins (Olsson et al. 2009; AU TGA 2008; Winston and Maimes 2007; Pizzorno and Murray 2006; Brown et al. 2002).

Dry non-standardized extract:

Up to 400 mg dry extract, per day, not to exceed 200 mg per single dose [1.5-5:1, 67-70% ethanol v/v] (EMEA 2012).

Tincture:

Up to 1.8 g dried root/rhizome, per day [1:4; up to 7.2 ml] (Winston and Maimes 2007)

Directions for use

Not to be taken immediately before bedtime (Iovieno et al. 2011; Pizzorno and Murray 2006; Kelly 2001).

Duration of use

Statement(s) to the effect of

No statement required.

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

- ▶ If symptoms persist or worsen, consult a health care practitioner.
- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use (EMA 2012).
- ▶ If you are taking antidepressant medication, consult a health care practitioner prior to use (Iovieno et al. 2011; Olsson et al. 2009; Brown et al. 2002).
- ▶ If you are taking hormone replacement therapy (HRT) or birth control pills, consult a health care practitioner prior to use (HC 2013; Brown et al. 2002).

Contraindication(s)

If you have bipolar disorder or bipolar spectrum disorder, do not use this product (Iovieno et al. 2011; Winston and Maimes 2007; Brown et al. 2002).



Known adverse reaction(s)

If you experience irritability or insomnia, discontinue use (Pizzorno and Murray 2006; Kelly 2001).

Non-medicinal ingredients

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

Storage conditions

Statement(s) to the effect of

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (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 2012 April 19]. 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 2012 December 3]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_Community_herbal_monograph/2012/05/WC500127863.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 2011 February 2]. Available from: http://www.swsbm.com/FelterMM/Felters_Materia_Medica.pdf

HC 2013: Health Canada. Canada Vigilance Adverse Reaction Online Database. Ottawa (ON): Marketed Health Products Directorate, Health Canada. [Accessed 2013 March 08]. Available from: <http://webprod3.hc-sc.gc.ca/arquery-rechercheei/index-eng.jsp>

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 cassiae* 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 2007: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. National Germplasm Resources Laboratory, Beltsville (MD). [*Rhodiola rosea* L. Last updated 2007 May 29; Accessed 2013 April 12]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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. [*Rhodiola rosea* L. (accepted name), *Sedum rosea* (L.) Scop. (synonym); Accessed 2012 November 30] Available from: <http://www.catalogueoflife.org/annual-checklist>

Noreen EE, Buckley JG, Lewis SL, Brandauer J, Stuemfle 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, 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.