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


References reviewed


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


