

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

February 25, 2019

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

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(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 	Dried

References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000; Source materials: 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.

The acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



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) (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

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-Standardised Dry Ethanolic Extracts

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 and Cognitive Function

Methods of preparation: Standardized extracts

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

Methods of preparation: Non-Standardised Dry Ethanolic Extracts

144 - 400 milligrams of dry extract and not to exceed a 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).

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 pills (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

No statement required.

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.

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