

NATURAL HEALTH PRODUCT

GRAPE SEED EXTRACT

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 labels 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

August 28, 2018

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) |
| Grape seed extract | Grape seed extract | <i>Vitis vinifera</i> | Seed |

References: Sano et al. 2007; Common name: Sano et al. 2007; Source material: USDA 2018, Sano et al. 2007, Henriot 1993.

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 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)

- ▶ Source of/Provides antioxidants (Sano et al. 2007; Natella et al. 2002; Bagchi et al. 2000; Bagchi et al. 1998).
- ▶ Helps to relieve symptoms related to non-complicated chronic venous insufficiency (CVI), such as sensation of swelling, heaviness and tingling of the legs (Henriet 1993; Henriet 1988; Thébaut et al. 1985; Delacroix et al. 1981; Sarrat 1981).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Antioxidant

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Not to exceed 475 milligrams of grape seed extract, per day; standardized to 70-85% oligomeric proanthocyanidins (OPC) (Sano et al. 2007; Natella et al. 2002).

Relief of symptoms related to non-complicated CVI

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

150 - 475 milligrams of grape seed extract, per day; standardized to 80-85% oligomeric proanthocyanidins (OPC) (Sano et al. 2007; Henriet 1993; Henriet 1988; Thébaut et al. 1985; Delacroix 1981; Sarrat 1981)

Direction(s) for use

No statement required.

Duration(s) of use

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 3 months (Sano et al. 2007).



Relief of symptoms related to non-complicated CVI

Use for at least 1 month to see beneficial effects (Thébaud et al. 1985; Delacroix 1981; Sarrat 1981).

Risk information :

Caution(s) and warning(s)

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

Relief of symptoms related to non-complicated CVI

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

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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