

NATURAL HEALTH PRODUCT

GENTIAN – *GENTIANA LUTEA*

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 statements are synonymous. Either term or statement may be selected by the applicant.

Date

July 1, 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>Gentiana lutea</i>	<ul style="list-style-type: none"> ▶ Bitterwort ▶ Gentian ▶ Gentian-root ▶ Yellow gentian 	<i>Gentiana lutea</i>	Root	Dried

References: Proper name: USDA 2019; Common names: McGuffin et al. 2000, Wiersema and León 1999; Source material: Blumenthal et al. 2000.

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)

- ▶ Traditionally used in Herbal Medicine to help relieve digestive disturbances (such as dyspepsia) (Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Felten and Lloyd 1983; Grieve 1971).
- ▶ Traditionally used in Herbal Medicine as a digestive tonic and bitter to help stimulate appetite and aid digestion (stomachic) (Mills and Bone 2005; Wichtl 2004; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Felten and Lloyd 1983; Grieve 1971).
- ▶ Traditionally used in Herbal Medicine to help prevent nausea (anti-emetic) (Bradley 1992; Williamson et al. 1988).
- ▶ Used in Herbal Medicine to help increase bile flow (cholagogue) (Wichtl 2004; Hoffmann 2003; Blumenthal et al. 2000).

The following combined use(s) or purpose(s) is/are also acceptable:

Traditionally used in Herbal Medicine as a digestive tonic and bitter to help stimulate appetite, aid digestion and help relieve digestive disturbances (Mills and Bone 2005; Wichtl 2004; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Felten and Lloyd 1983; Grieve 1971).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

0.1 - 6 grams of dried root, per day (Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992)

Direction(s) for use (optional)

Take 15 - 60 minutes before meals (ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992).

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 breastfeeding.

Contraindication(s)

Do not use this product if you are pregnant or have acute stomach irritation, inflammation and stomach or duodenal ulcers (ESCOP 2003; Hoffmann 2003; Brinker 2001; Bradley 1992; Morimoto et al.1983).

Known adverse reaction(s)

Some people may experience headaches (ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000).

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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