

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 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 on the label.

Date

January 10, 2025

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

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

Proper name(s)	Common name(s)	Source information		
		Source material(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	Dry

References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013, Wiersema and León 1999; Source information: 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.



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

Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to help prevent nausea and to help relieve digestive disturbances).
- **For multi-ingredient products:**
 - To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Gentian is traditionally used in Herbal Medicine to help prevent nausea).
 - When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

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

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

***Note:** Solvents allowed for the method of preparation “Non-Standardized Extracts (Dry extract)” as part of this monograph are ethanol and/or water only.



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)

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician if** symptoms persist or worsen.
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if** you are breastfeeding.

Contraindication(s)

- **Do not use if** you are pregnant (Hoffmann 2003; Morimoto et al.1983).
- **Do not use if** you have stomach or duodenal acute inflammation or ulcer (Brinker 2010; ESCOP 2003; Bradley 1992).

Known adverse reaction(s)

When using this product you 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

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

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.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredient in each capsule <i>Gentiana lutea</i> (Gentian) extract X:1 XX mg Equivalent to YY g of dried root
Uses <ul style="list-style-type: none"> • (Traditionally) used in Herbal Medicine to help prevent nausea. • (Traditionally) used in Herbal Medicine to help relieve digestive disturbances. • Used in Herbal Medicine to help increase bile flow.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Do not use if • you are pregnant • you have stomach or duodenal acute inflammation or ulcer.
Ask a health care practitioner before use if you are breastfeeding.
When using this product you may experience headaches.
Ask a health care practitioner if symptoms persist or worsen.
Directions Adults 18 years and older: • Take X capsule(s), X time(s) per day • Take 15 – 60 minutes before meals.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

References cited

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