Health Canada Santé Canada

GENTIAN

Date: February 27, 2008

Proper name(s): *Gentiana lutea* L. (Gentianaceae) (USDA 1994)

Common name(s): Gentian, yellow gentian (McGuffin et al. 2000; Wiersema and León 1999)

Source material(s): Root (Blumenthal et al. 2000)

Route(s) of administration: Oral

Dosage form(s): Those suited to the allowable route(s) of administration. This monograph is not intended to include food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s): Statement(s) to the effect of:

- Traditionally used in Herbal Medicine to help relieve digestive disturbances/dyspepsia (Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Felter and Lloyd 1983 [1898]; Grieve 1971 [1931]).
- 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; Felter and Lloyd 1983 [1898]; Grieve 1971 [1931]).
- 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).

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Dose(s): Preparations equivalent to 0.1-6 g dried root, per day (Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992)

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

See Appendix 1 for examples of appropriate dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use: No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

- Consult a health care practitioner if symptoms persist or worsen.
- Consult a health care practitioner prior to use if you are breastfeeding.

Contraindication(s):

- Do not use if you have acute stomach irritation, inflammation, and stomach or duodenal ulcers (ESCOP 2003; Brinker 2001; Bradley 1992).
- Do not use if you are pregnant (Hoffmann 2003; 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 NHPD *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.

Specifications:

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- The medicinal ingredient may comply with the specifications outlined in the Gentian Monograph published in the British

Pharmacopoeia or the Gentian Root Monograph published in the European Pharmacopoeia.

References cited:

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Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

Dried root:

- 1.8-6 g, per day (Mills and Bone 2005)
- 2-4 g, per day (Blumenthal et al. 2000)

Infusion or decoction:

- 1.8-6 g dried root, per day (Mills and Bone 2005)
- 0.1-2 g dried root, 1-3 times per day (ESCOP 2003)
- 1-2 g dried root, 2-3 times per day (Blumenthal et al. 2000)
- 0.6-2 g dried root, 3 times per day (Bradley 1992)

Directions for use (infusion): Pour 150 ml of boiling water (Blumenthal et al. 2000) over dried root, steep for 5 minutes and strain (Wichtl 2004).

Fluidextract:

- 2-4 g dried equivalent, per day
  (1:1, 2-4 ml) (Blumenthal et al. 2000)
- 1-2 g dried equivalent, 2-3 times per day
  (1:1, 1-2 ml) (Blumenthal et al. 2000)

Tincture:

- 0.35-1 g dried equivalent, per day
  (1:2, 0.7-2 ml) (Mills and Bone 2005)
- 0.6-2.4 g dried equivalent, per day
  (1:5, 3-12 ml) (Mills and Bone 2005)
- 0.2 g dried equivalent, 1-3 times per day
  (1:5, 45-70% ethanol, 1 ml) (ESCOP 2003)
- 0.2-0.4 g dried equivalent, 3 times per day
  (1:5, 40% alcohol, 1-2 ml) (Hoffmann 2003)
- 1-3 g dried equivalent, per day (Blumenthal et al. 2000)
- 0.2-0.8 g dried equivalent, 3 times per day
  (1:5, 45% ethanol, 1-4 ml) (Bradley 1992)

Solid extract: 0.2-0.4 g dried equivalent, 2-3 times per day
(3.5-4.5:1) (Blumenthal et al. 2000)