Conjugated Linoleic Acid

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CONJUGATED LINOLEIC ACID Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version-36K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) 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 ingredient(s) Preparation(s) Conjugated linoleic acid Conjugated linoleic acid CLA Conjugated linoleic acid Synthetic References: Proper name: Pariza 2004; Pariza et al. 2001; Common names: Pariza 2004; Pariza et al. 2001; Source information: FDA 2007; Pariza et al. 2001. 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) May help to support a modest improvement to body composition when used with a program of reduced intake of dietary calories and increased physical activity (Raff et al. 2009; Gaullier et al. 2007; Pinkoski et al. 2006; Gaullier et al. 2004; Kamphuis et al. 2003). May help to support a modest reduction in fat mass when used with a program of reduced intake of dietary calories and increased physical activity (Raff et al. 2009; Gaullier et al. 2007; Watras et al. 2007; Pinkoski et al. 2006; Gaullier et al. 2004). Note: The above uses can be combined on the product label (e.g., May help to support a modest reduction in fat mass and a modest improvement to body composition when used with a calorie-reduced diet and increased physical activity). Restrictions when this monograph is combined with other monographs (Class II and III applications): If a body composition/reduction of fat mass claim is made: Improvement of body composition/reduction of fat mass is a long-term process and must therefore be associated with a long-term intervention. Medicinal ingredient with diuretic properties may be included in products associated with weight management, however no diuretic claim can be applied as it is associated with a short-term duration of use (occasional use only). Stimulant laxatives cannot be present at therapeutic dose in products associated with weight management as their short term duration of use is not compatible with the duration of use for weight management. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 3 - 5 grams of CLA, per day (Raff et al. 2009; Gaullier et al. 2007; Watras et al. 2007; Pinkoski et al. 2006; Gaullier et al. 2004; Kamphuis et al. 2003). Note: Additional information not to be submitted with the compendial PLA (although the quantity of CLA-rich oil may be requested at the NNHPD's discretion): Approximately 4-6.5 g CLA-rich oil provides 3-5 g CLA. Direction(s) for use Optional: Take with food (Watras et al. 2007; Kamphuis et al. 2003). Duration(s) of use Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 months (Gaullier et al. 2007; Watras et al. 2007; Gaullier et al. 2005; Gaullier et al. 2004). Risk information Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are obese or have cardiovascular disease (CVD) risk factors (Tholstrup et al. 2008; Gaullier et al. 2007; Steck et al. 2007; Larsen et al. 2006; Taylor et al. 2006; Gaullier et al. 2005; Smedman et al. 2005; Gaullier et al. 2004; Basu et al. 2000a,b). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if your goal is to achieve weight loss. Contraindication(s) Do not use if you are pregnant (HC 2010). Do not use if you have cardiovascular disease (CVD), diabetes, metabolic syndrome or insulin resistance (Tholstrup et al. 2008; Gaullier et al. 2007; Steck et al. 2007; Larsen et al. 2006; Taylor et al. 2006; Gaullier et al. 2005; Smedman et al. 2005; Gaullier et al. 2004; Moloney et al. 2004; Basu et al. 2000a,b). Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Gaullier et al. 2007; Pinkoski et al. 2006; Berven et al. 2000; Blankson 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. The CLA-rich oil must comply with the chemical specifications: CLA total ≥ 78%; CLA (c9t11 + t10,c12 isomers) ≥ 74%; CLA c9,t11 isomers ≥ 36%; CLA t10,c12 isomers ≥ 36%; CLA trans, trans ≤ 3% (FDA 2007). The maximum peroxide value derived from CLA-rich oil must be ≤ 1 meq O2/kg and be in accordance with the methods set out by the American Oil Chemists' Society (AOCS) and/or Pharmacopoeial analytical methods. This specification is necessary to ensure the oxidative stability of the CLA. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Basu S, Risérus U, Turpeinen A, Vessby B. 2000a. Conjugated linoleic acid induces lipid peroxidation in men with abdominal obesity. Clinical Science 99(6):511-516. Basu S, Smedman A, Vessby B. 2000b. Conjugated linoleic acid induces lipid peroxidation in humans. FEBS Letters 468(1):33-36. Berven G, Bye A, Hals O, Blankson H, Fagertun H, Thom E, Wadstein J, Gudmundsen O. 2000. Safety of conjugated linoleic acid (CLA) in overweight and obese human volunteers. European Journal of Lipid Science and Technology 102(7):455-462. Blankson H, Stakkestad JA, Fagertun H, Thom E, Wadstein J, Gudmundsen O. 2000. Conjugated linoleic acid reduces body fat mass in overweight and obese humans. The Journal of Nutrition 130(12):2943-2948. FDA 2007: United States Food and Drug Administration. 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MEDICINAL INGREDIENT(S)

Must be chosen from the currentNatural Health Products Ingredients Database (NHPID)and must meet the limitations outlined in the database.

DOSAGE FORM(S)

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.

RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are obese or have cardiovascular disease (CVD) risk factors (Tholstrup et al. 2008; Gaullier et al. 2007; Steck et al. 2007; Larsen et al. 2006; Taylor et al. 2006; Gaullier et al. 2005; Smedman et al. 2005; Gaullier et al. 2004; Basu et al. 2000a,b). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if your goal is to achieve weight loss. Contraindication(s) Do not use if you are pregnant (HC 2010). Do not use if you have cardiovascular disease (CVD), diabetes, metabolic syndrome or insulin resistance (Tholstrup et al. 2008; Gaullier et al. 2007; Steck et al. 2007; Larsen et al. 2006; Taylor et al. 2006; Gaullier et al. 2005; Smedman et al. 2005; Gaullier et al. 2004; Moloney et al. 2004; Basu et al. 2000a,b). Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Gaullier et al. 2007; Pinkoski et al. 2006; Berven et al. 2000; Blankson et al. 2000).

NON-MEDICINAL INGREDIENTS

Must be chosen from the currentNatural Health Products Ingredients Database (NHPID)and must meet the limitations outlined in the database.

STORAGE CONDITION(S)

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. The CLA-rich oil must comply with the chemical specifications: CLA total \geq 78%; CLA (c9t11 + t10,c12 isomers) \geq 74%; CLA c9,t11 isomers \geq 36%; CLA t10,c12 isomers \geq 36%; CLA trans, trans \leq 3% (FDA 2007). The maximum peroxide value derived from CLA-rich oil must be \leq 1 meq O2/kg and be in accordance with the methods set out by the American Oil Chemists' Society (AOCS) and/or Pharmacopoeial analytical methods. This specification is necessary to ensure the oxidative stability of the CLA.

Proper name(s)	Common name(s)	Source information	
Source ingredient(s)	Preparation(s)		
Conjugated linoleic acid	Conjugated linoleic acidCLA	Conjugated linoleic acid	Synthetic