

Calcium-Potassium Salt of Hydroxycitric Acid

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CALCIUM-POTASSIUM SALT OF HYDROXYCITRIC 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 - 117 K) 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 31, 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) Common name(s) Part(s) Preparation(s) Calcium/Potassium Salt of Hydroxycitric Acid Calcium-potassium salt of (-)-hydroxycitric acid Calcium/Potassium Salt of Hydroxycitric Acid Calcium-potassium salt of (-)-hydroxycitric acid *Garcinia gummi-guta* N/A Fruit peel N/A Calcium-potassium salt of (-)-hydroxycitric acid N/A Synthetic References: Proper names: Preuss et al. 2004a, Preuss et al. 2004b; Common names: Preuss et al. 2004a, Preuss et al. 2004b; Source materials: Hayamizu et al. 2008, Preuss et al. 2004a, Preuss et al. 2004b. 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) Could help to temporarily increase satiety/feeling of fullness (Westerterp-Plantega and Kovacs 2002). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 1500-5000 milligrams, per day; Not to exceed 500-2000 milligrams per single dose (Preuss et al. 2004a; Preuss et al. 2004b; Westerterp-Plantega and Kovacs 2002). Potency: 60% Hydroxycitric acid 11% Calcium 16% Potassium Direction(s) for use Take before meals, a few hours before or after taking other medications or natural health products (Martindale 2009; ASHP 2005; CPhA 2001). 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 prior to use if you are pregnant or breastfeeding. Contraindication(s) Products providing 350-747 mg potassium per day, or more than 200 mg potassium per dose: Do not use this product if you have gastrointestinal ulceration or obstruction (Martindale 2009; CPhA 2001). Known adverse reaction(s) Products providing 350-747 mg potassium per day, or more than 200 mg potassium per dose: May cause nausea, vomiting, diarrhea, abdominal cramps; stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms are severe (Martindale 2009; CPhA 2001). 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 . References cited ASHP 2005: American Society of Health-System Pharmacists. American Hospital Formulary Service (AHFS) Drug Information. Philadelphia (PA): Lippincott Williams and Wilkins; 2005 CPhA 2001: Canadian Pharmacists Association. Compendium of Nonprescription Products: Companion to CPS. Ottawa (ON): Canadian Pharmacists Association; 2001 Hayamizu K, Tomi H, Kaneko I, Shen M, Soni MG, Yoshino G. Effects of *Garcinia cambogia* extract on serum sex hormones in overweight subjects. *Fitoterapia* 2008; 79: 255-261 Martindale 2009: Sweetman SC (ed), Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; Copyright 1933-2010. [Accessed 2018 June 1]. Available from: <http://www.medicinescomplete.com> Preuss HG, Bagchi D, Bagchi M, Rao CVS, Dey DK, Satyanarayana S. 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MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

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.

DOSE(S)

Hayamizu K, Ishii Y, Shigematsu N, Okuhara Y, Tomi H, Furuse M, Yoshino G, Shimasaki H. Safety of Garcinia cambogia extract in healthy men: high-doses administration study I. Journal of Oleo Science. 2003a; 52(9): 499-504 Hayamizu K, Ishii Y, Kaneko I, Shen M, Okuhara Y, Shigematsu N, Tomi H, Furuse M, Yoshino G, Shimasaki H. Effects of Garcinia cambogia (Hydroxycitric acid) on visceral fat accumulation: A double-blind, randomized, placebo-controlled trial. Current Therapeutic Research 2003b; 64 (8): 551-567 HC 2011: Health Canada. Canada Vigilance Adverse Reaction Online Database. Ottawa (ON): Marketed Health Products Directorate, Health Canada; 2011. [Accessed 2012 January 9]. Available from: <http://webprod3.hc-sc.gc.ca/arquery-recherche/index-eng.jsp> Heymsfield SB, Allison DB, Vasselli JR, Pietrobelli A, Greenfield D, Nunez C. Garcinia cambogia (Hydroxycitric acid) as a potential antiobesity agent, a randomized controlled trial. Journal of the American Medical Association 1998; 280(18): 1596-1600 IOM 2005: Institute of Medicine. Panel on Dietary Reference Intakes for Electrolytes and Water, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. Washington (DC): National Academies Press. Ishii Y, Kaneko I, Shen M, Hayamizu K, Shigematsu N, Tomi H, Yoshino G, Shimaski H. Safety of Garcinia cambogia extract in healthy volunteers: High-dose administration study II. Journal of Oleo Science 2003; 52(12): 663-671 Jena BS, Jayaprakasha GK, Singh RP, Sakariah KK. Chemistry and biochemistry of (-)-hydroxycitric acid from Garcinia. Journal of agricultural and food chemistry 2002; 50: 10-22 Kaats G, Pullin D, Parker L, Keith S. 1996 [as reviewed in Heymsfield et al. 1998 and Soni et al. 2004] Kim JE, Jeon SM, Park KH, Lee WS, Jeong TS, McGregor RA, Choi MS. Does Glycine max leaves or Garcinia Cambogia promote weight-loss or lower plasma cholesterol in overweight individuals: a randomized control trial. Nutrition Journal 2011; 10: 94 Kiyose C, Ogino S, Kubo K, Takeuchi M, Saito M. Relationship

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RISK INFORMATION

Caution(s) and warning(s) Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding. Contraindication(s) Products providing 350-747 mg potassium per day, or more than 200 mg potassium per dose: Do not use this product if you have gastrointestinal ulceration or obstruction (Martindale 2009; CPhA 2001). Known adverse reaction(s) Products providing 350-747 mg potassium per day, or more than 200 mg potassium per dose: May cause nausea, vomiting, diarrhea, abdominal cramps; stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms are severe (Martindale 2009; CPhA 2001).

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.

STORAGE CONDITION(S)

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 theNHPID.

REFERENCES

Route of administration Oral

er name(s)	Common name(s)	Source material(s)		
er name(s)	Common name(s)	Part(s)	Preparation(s)	
um/Potassium Salt of Hydroxycitric Acid	Calcium/Potassium Salt of Hydroxycitric Acid	Calcium-potassium salt of (-)-hydroxycitric acid	N/A	Fruit peel
	Calcium-potassium salt of (-)-hydroxycitric acid	N/A	Synthetic	