5-HTP

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5-HTP 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 - 80 KB) 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 August 28, 2024 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) Source material(s) Part(s) 5-Hydroxyt-tryptophan L-5-Hydroxytryptophan L-5-Hydroxytryptophan N/A Griffonia simplicifolia Seed L-5-HTP 1 N/A N/A N/A Escherichia coli Whole cell for biosynthesis N/A Saccharomyces cerevisiae Whole cell for biosynthesis References: Proper names: RSC 2023; Common names: RSC 2023; Source information: Lemaire and Adosraku 2002, Fellows and Bell 1970. 1 Synthetic 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) Helps (to) promote healthy mood balance (Pöldinger et al. 1991; Zmilacher et al. 1988; Nakajima et al. 1978). Helps (to) relieve sleep disturbances associated with mood imbalance (Sutanto et al. 2024; Poldinger et al. 1991; Soulairac and Lambinet 1988) Helps (to) relieve symptoms of fibromyalgia (Nicolodi and Sicuteri 1996; Sarzi Puttini and Caruso 1992; Caruso et al. 1990). Helps (to) reduce the severity and duration of migraine headaches when taken as a preventative (prophylactic) (Titus et al. 1986; Bono et al. 1984; Sicuteri 1973). To be used with a program of reduced intake of dietary calories and increased physical activity (if possible) to help in weight management by reducing carbohydrate cravings (Cangiano et al.1998; Cangiano et al. 1992; Ceci et al. 1989). Restrictions when this monograph is combined with other monographs (Class II and III applications): If a weight management claim is made: Weight management is a long-term process and must therefore, be associated with a long-term intervention. Medicinal ingredient with diuretic properties may be included in weight management products, 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 weight management products 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) Healthy mood balance 150 - 300 milligrams of 5-HTP, per day (Pöldinger et al. 1991; Nakajima et al. 1978). Fibromyalgia symptoms 300 - 400 milligrams of 5-HTP, per day; Not to exceed 300 milligrams per single dose (Nicolodi and Sicuteri 1996; Caruso et al. 1990). Migraine prophylaxis 200 - 600 milligrams of 5-HTP, per day; Not to exceed 300 milligrams per single dose (Titus et al. 1986; Sicuteri 1973). Weight management 750 - 900 milligrams of 5-HTP, per day; Not to exceed 300 milligrams per single dose (Cangiano et al. 1998; Cangiano et al. 1992; Ceci et al. 1989). Sleep disturbances 100 - 200 milligrams of 5-HTP, per day (Sutanto et al. 2024; Soulairac and Lambinet 1988; Soulairac and Lambinet 1977; Wyatt et al. 1971). Direction(s) for use All uses To minimize the risk of gastrointestinal side effects, start at lower dose and slowly increase to effective dose over 2-week period (Birdsall 1998). All uses (excluding weight management) Take with food (Pöldinger et al. 1991). Weight management Take 30 minutes before meals (Cangiano et al. 1998; Cangiano et al. 1992; Ceci et al. 1989). Duration(s) of Use Healthy mood balance; Fibromyalgia symptoms; Migraine prophylaxis; Sleep disturbances Use for at least 2 weeks to see beneficial effects (Jangid et al. 2013; Caruso et al. 1990; Nakajima et al. 1978; Sicuteri 1973). Weight management (products providing over 600 mg 5-HTP, per day) Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 12 weeks (Cangiano et al. 1992). Risk Information Caution(s) and warning(s) All uses Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking carbidopa or health products with serotonergic activity such as mood balance supplements, cough medication containing dextromethorphan, pain killers or medications for nausea or migraine (Mayo Clinic Staff 2022; Patel

and Marzella 2017; Turner et al 2006). When using this product exercise caution while driving or using machinery, as you may experience drowsiness (Berardi et al. 2002). Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. All uses (excluding weight management) Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are pregnant or breastfeeding. Weight management Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are breastfeeding. Healthy mood balance; practitioner/health symptoms Ask а health care care provider/health professional/doctor/physician before use if you have a psychological disorder such as anxiety or depression. Contraindication(s) All uses Do not use if you have scleroderma (Lampert et al. 1992; Sternberg et al. 1980). Do not use if you are taking antidepressants (Mayo Clinic Staff 2022; Patel and Marzella 2017). Weight management Do not use if you are pregnant (HC 2010). Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Turner et al. 2006; Byerley et al. 1987). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience skin hardening, pain or stiffness of muscles or joints, tremors, agitation/confusion, or an increased heart rate (Boyer 2023; Varga 2023; Mayo Clinic Staff 2022; Patel and Marzella 2017; Das et al. 2004; Erner et al. 2003; Lampert et al. 1992; Sternberg et al. 1980). 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. References Cited Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollings CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13 th edition. Washington (DC): American Pharmaceutical Association; 2002. Birdsall TC. 5-Hydroxytryptophan: a clinically-effective serotonin precursor. Alternative Medicine Review 1998;3(4):271-280. Bono G, Micieli G, Sances G, Calvani M, Nappi G. L-5HTP treatment in primary headaches: an attempt at clinical identification of responsive patients. Cephalalgia 1984;4(3):159-165. 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International Journal of Obesity and Related Metabolic Disorders 1993;17(9):513-520. Renson J. Goodwin F, Weissbach H, Udenfriend S. Conversion of tryptophan to 5hydroxytryptophan by phenylalanine hydroxylase. Biochemical and Biophysical Research Communications 1961;6(1):20-23. Ribeiro CA. L-5-Hydroxytryptophan in the prophylaxis of chronic tension-type headache: a double-blind, randomized, placebo-controlled study. For the Portuguese Head Society. Headache 2000;40(6):451-456. Santucci M, Cortelli P, Rossi PG, Baruzzi A, Sacquegna T. L-5-hydroxytryptophan versus placebo in childhood migraine prophylaxis: a double-blind crossover study. Cephalalgia 1986;6(3):155-157. Schruers K, Van Diest R, Overbeek T, Griez E. Acute L-5-hydroxytryptophan administration inhibits carbon dioxide-induced panic in panic disorder patients. Psychiatry Research 2002;113(3):237-243. Shaw K, Turner J, DelMar C. Tryptophan and 5-hydroxytryptophan for depression. 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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 Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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.

DOSE(S)

Webb M, Kirker JG. Severe post-traumatic insomnia treated with L-5-hydroxytryptophan. Lancet 1981;1(8234):1365-1366. Westenberg HG, Gerritsen TW, Meijer BA, Van Praag HM. Kinetics of I-5-hydroxytryptophan in healthy subjects. Psychiatry Research 1982;7(3):373-385. Yamada J, Sugimoto Y, Ujikawa M. Involvement of leptin in hypophagia induced by the serotonin precursor 5-hydroxytryptophan (5-HTP) in mice. Biological and Pharmaceutical Bulletin 2006;29(3):557-559. Zarcone VP, Berger PA, Brodie KH, Sack R, Barchas JD. The indoleamine hypothesis of depression: an overview and pilot study. Diseases of the Nervous System 1977;38(8):646-653.

RISK INFORMATION

Caution(s) and warning(s) All uses Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking carbidopa or health products with serotonergic activity such as mood balance supplements, cough medication containing dextromethorphan, pain killers or medications for nausea or migraine (Mayo Clinic Staff 2022; Patel and Marzella 2017; Turner et al 2006). When using this product exercise caution while driving or using machinery, as you may experience drowsiness (Berardi 2002).Ask а health care practitioner/health care provider/health professional/doctor/physician if symptoms persist or worsen. All uses (excluding weight management) Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are pregnant or breastfeeding. Weight management Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you are breastfeeding. Healthy mood balance; Fibromyalgia symptoms Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a psychological disorder such as anxiety or depression. Contraindication(s) All uses Do not use if you have scleroderma (Lampert et al. 1992; Sternberg et al. 1980).Do not use if you are taking antidepressants (Mayo Clinic Staff 2022; Patel and Marzella 2017). Weight management Do not use if you are pregnant (HC 2010). Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Turner et al. 2006; Byerley et al. 1987). Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience skin hardening, pain or stiffness of muscles or joints, tremors, agitation/confusion, or an increased heart rate (Boyer 2023; Varga 2023; Mayo Clinic Staff 2022; Patel and Marzella 2017; Das et al. 2004; Erner et al. 2003; Lampert et al. 1992; Sternberg et al. 1980).

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.

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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details.

REFERENCES

Route of Administration Oral

e(s)	Common name(s)	Source information	
ient(s)	Source material(s)	Part(s)	
ryptophanL-5-Hydroxytryptoph	alb-5-HTPL-5-Hydroxytryptophan	N/A	Griffonia simplicifolia
	N/A	N/A	
	Escherichia coli	Whole cell for biosynthesis	
	Saccharomyces cerevisiae	Whole cell for biosynthesis	