Lactase

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Lactase (PDF Version - 76 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 January 31, 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 Proper name(s)Source material(s) Part(s) beta-D-galactoside galactohydrolase beta-galactosidase beta-galactosidase Lactase Tilactase Aspergillus flavus var. oryzae Whole References: Proper names: IUBMB 1980; Common names: IUBMB 1980; Source information: CABI 2012; Bisby et al. 2010. 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. Note: Liquid and liquid-containing dosage forms (e.g., capsule, soft; spray) are not acceptable as Class II applications when lactase is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application. Use(s) or Purpose(s) Digestive enzyme Digestive enzyme/lactase to assist in the digestion of foods containing lactose (e.g. dairy foods, milk) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987). Helps prevent symptoms of lactose intolerance (including gas, bloating, cramping and diarrhea) (Ramirez et al. 1994; Lin et al. 1993; Biller et al. 1987; Moskovitz et al. 1987). Note: The above uses can be combined on the product label (e.g., Digestive enzyme that helps prevent symptoms of lactose intolerance). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Digestive enzyme Not to exceed 54,000 FCC ALU of enzymatic activity, per day; and 18,000 FCC ALU per single dose (FCC 2024; Ramirez et al. 1994; Lin et al. 1993). Lactose digestion/Symptoms of lactose intolerance 3,000 - 54,000 FCC ALU of enzymatic activity, per day; not to exceed 18,000 FCC ALU per single dose (FCC 2024; Ramirez et al. 1994; Lin et al. 1993). Notes The Quantity per dosage unit must be the enzymatic activity (FCC unit). The quantity of the enzymatic preparation in mg or ml should also be included as additional quantity. One lactase unit (ALU) is defined as that quantity of enzyme that will liberate o -nitrophenol at a rate of 1 µmol/min under the conditions of the assay (FCC 2024). Direction(s) for use Take with or immediately before a meal/food. Duration(s) of Use All products Ask a health care practitioner/health care provider/health care professional/doctor/physician for prolonged use. Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Groff and Gropper 2000). Lactose digestion/Symptoms of lactose intolerance Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if gastro-intestinal disturbance and/or hypersensitivity/allergy occur (HC 2011). 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 . Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. 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. Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient. The specifications must include testing for enzymatic activity of the medicinal ingredient at appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): Lactase (Acid) (?-Galactosidase) activity (ALU). Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of the shelf life indicated on the product label. References Cited Biller JA, King S, Rosenthal A, Grand RJ. 1987. Efficacy of lactase-treated milk for lactose- intolerant pediatric patients.

The Journal of Pediatrics 111: 91-94. Bisby F, Roskov Y, Culham A, Orrell T, Nicolson D, Paglinawan L. Bailly N, Appeltans W, Kirk P, Bourgoin T, Baillargeon G, Ouvrard D, editors. Species 2000 & ITIS Catalogue of Life. Reading (GB): Species 2000. [Source database: Species Fungorum 9.0, Sep 2010; Accessed 2024 November 21]. Available from: http://www.catalogueoflife.org CABI 2012: Centre for Agriculture and Bioscience International. Index Fungorum. Wallingford (GB): CABI (Centre for Agriculture and Bioscience International); 2012. [Accessed 2024 November 21]. Available from: http://www.speciesfungorum.org FCC 2024: Food Chemicals Codex, 14 th edition. Rockville (MD): The United States Pharmacopeial Convention; 2024. HC 2011: Health Canada. 2011. Canada Vigilance Online Database. Ottawa (ON): Health Canada. [Updated 2011 September 30; Accessed 2024 November 21]. Available from: http://hc-sc.gc.ca/dhp-mps/medeff/databasdon/index-eng.php Groff J, Gropper S. 2000. Advanced Nutrition and Human Metabolism, 3rd edition. Belmont (CA): Wadsworth/Thomson Learning. IUBMB 1980: Nomenclature Committee of the International Union of Biochemistry and Molecular Biology. [Internet]. London (GB): Queen Mary, University of London [?- galactosidase: EC 3.2.1.23. created 1961, modified 1980; Accessed 2012 March 28]. Available from: http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/2/1/23.html Lin MY, Dipalma JA, Martini MC, Gross CJ, Harlander SK, Savaiano DA. 1993. Comparative effects of exogenous lactase (beta-galactosidase) preparations on in vivo lactose digestion.Digestive Diseases and Sciences 38(11):2022-2027. Moskovitz M, Curtis C, Gavaler J. 1987. Does oral enzyme replacement therapy reverse intestinal lactose malabsorption? The American Journal of Gastroenterolgy 82(7):632-635. Ramirez FC, Lee K, Graham DY. 1994. All lactase preparations are not the same: results of a prospective, randomized, placebo-controlled trial. The American Journal of Gastroenterology 89(4):566-570. USP-NF 2024: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2024. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural 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. Note:Liquid and liquid-containing dosage forms (e.g., capsule, soft; spray) are not acceptable as Class II applications when lactase is combined with non-enzymatic ingredients as the enzyme activity may be impacted. These products may be submitted as a Class III application.

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Groff and Gropper 2000). Lactose digestion/Symptoms of lactose intolerance Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if gastro-intestinal disturbance and/or hypersensitivity/allergy occur (HC 2011).

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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural 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.Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient.The specifications must include testing for enzymatic activity of the medicinal ingredient at appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): Lactase (Acid) (?-Galactosidase) activity (ALU).Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of the shelf life indicated on the product label.

Proper name(s)	Common name(s)	Source information	
Proper name(s)Source material(s)	Part(s)		
beta-D-galactoside galactohydrolasebeta-galactosidase	beta-galactosidaseLactaseTilactase	Aspergillus flavusvar.oryzae	Whole